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(71)(72) Applicant and Inventor: AL-SAADON, Khalid [SA/CA]; 903-751 Parkdale Avenue, Ottawa, Ontario K1Y 1J7 (CA).

(74) Agent: MACRAE & CO.; P.O. Box 806, Station B, Ottawa, Ontario K1P 5T4 (CA).

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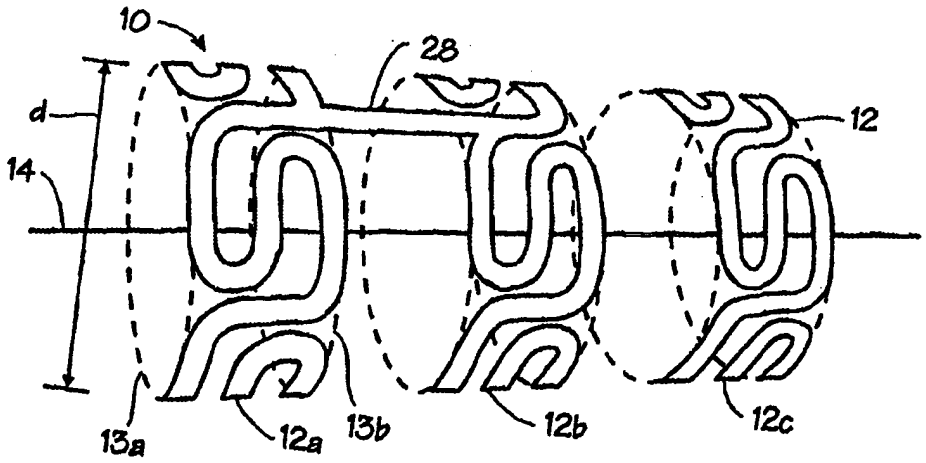

(57) Abstract

An expandable endovascular medical tubular stent is a supporting device intended to maintain the walls of anatomical body channels or vessels, the stent being expandable within the vessel by an angioplasty balloon associated with a catheter thereby dilating and expanding the lumen of a vessel. The stent comprises an arrangement of a plurality of radially expandable, serpentine members arranged in interconnected rings. Upon inflation of the balloon, the stent expands in both radial and longitudinal directions in relation to the amount of radially-outwardly directed force by the balloon. The stent is designed such that during expansion, local plastic deformation occurs only at the points of inflection distributed throughout the rings. Expansion is limited in proportion to the amount of expansion to ensure the resulting expanded stent is within material fracture limits and that adequate wall supporting structure is provided thereby.

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EXPANDABLE ENDOVASCULAR MEDICAL TUBULAR STENT

Technical Field

The present invention relates to expandable intravascular medical tubular stents which are applied within the peripheral or coronary arteries of a living animal or human being to maintain patency after a balloon angioplasty, and also relates more generally to stents which may be applied to the pathology of other anatomical canals, such as the venous, biliary, esophagus, urinary, and so forth.

Background Art

Stents are generally tubular-shaped devices whose function is to hold open a segment of a vessel in the human body. The term "vessel" is intended to include any of the arteries and body passageways found in the human body.

Stents are of two types. The first comprises a generally non-elastic, metallic material which is radially expandable (i.e. plastically deformable) from the inside towards the outside under the effect of an inflatable balloon. The second comprises an elastic metallic material made of metal mesh whose diameter constricts under tension. This stent is introduced under tension into the lumen of the vessel whereupon release of the tension returns the stent to its relaxed, larger diameter state.

Further details of prior art stent structures may be found in U.S. Patent No. 5,514,154 (Lau et al); U.S. Patent No. 5,041,126 (Gainturo); U.S. Patent No. 4,655,771 (Wallsten); U.S. Patent No. 5,496,365 (Srgo); U.S. Patent No. 5,133,732 (Wiktor); U.S Patent No. 5,382,261 (Palmaz); U.S. Patent No. 5,102,417 (Palmaz); U.S. Patent No. 5,195,984 (Schatz); U.S Patent No. 5,776,183 (Kanesaka); U.S Patent No. 5,800,509 (Boneau); U.S. Patent No. 5,800,526 (Anderson et al); U.S. Patent No. 5,776,181 (Lee et al); U.S. Patent No. 5,800,508 (Goicoechea et al); U.S. Patent No. 5,776,161 (Globerman); U.S. Patent No. 5,755,776 (Al-Saadon); U.S. Patent No. 5,843,175 (Frantzen); and U.S. Patent No. 5,843,120 (Israel et al.). These patents are incorporated herein by reference in their entirety.

Although there are several existing devices, each suffers from variety of drawbacks which make them less than ideal. For example, lack of flexibility in the majority of previous art surgical stents makes it very difficult to access the tortuous nature of some arterial pathways, which may result in damage to the arterial wall during deployment of the stent.

Another problem which is present in most of the prior art stents is that the axial length of the stent shortens upon radial expansion, making it difficult for the operating physician to position the stent precisely within the artery or other body lumen.

Additionally, prior art stents have a relatively limited range of radial expansion due to their structure and, accordingly, such stents have to be provided in a variety of different non-expanded diameters to cover different vessel sizes after expansion. However, it is often difficult for the operating physician to accurately determine the exact final diameter size of the stent needed for proper vessel size. This may result in wall damage in the case of over-estimating of the final diameter size of the stent, or a sub-optimal result in the case of under-estimation of the final diameter size of the stent. In the latter case, since it usually impossible to remove the stent once expanded, an over-sized balloon may have to be employed to fracture the structure of the stent to the extent necessary to get good patency of the vessel wall. However, this may result in vessel wall damage or loss of the radial strength of the stent (which may cause re-stenosis), or procedure difficulty due to rupture of the balloon inside the vessel wall which may put the life of the patient in danger.

Preferably, the constricted diameter of the stent should be as small as possible in order to facilitate introduction of the stent into the vessel. Not only is the range of expansion affected by reducing the initial diameter of prior art stents, but at odds is that reducing the initial diameter of a stent tends to reduce its axial flexibility for a given tubular wall thickness.

Another problem present in some of the prior art surgical stents is the relatively loose geometry with large gaps or wire crossing which may result in relatively high re-stenosis rate of the stent either due to higher incidence of clot formation within the stent or due to weak radial force of the stent.

With my previous stent described in U.S. Patent 5,755,776, I manage to overcome most of the drawbacks that exist in the prior art surgical stents, except the necessity for a variety of different diameter size stents for different vessels sizes.

Summary of the Invention

The present invention provides a stent which has flexibility substantially along its longitudinal axis when in its initial, constricted state (i.e. before balloon expansion on a catheter) to allow it to easily pass through and along highly curved body vessels and fluid carrying tubes. In accordance with one aspect of the invention, there is provided an endovascular tubular stent

expandable between a first, constricted state and a second state of greater expanded diameter wherein the stent comprises in its constricted state:

a plurality of interconnected radially expandable rings each formed of a plurality of circumferentially extensible serpentine elements, each circumferentially extensible serpentine element comprising:

first and second generally circumferentially-extending members each having respective first and second ends, the first and second members being spaced-apart in the axial direction of the stent; and

a medial member connecting the second end of the first member with the first end of the second member such that at least a portion of the first member circumferentially overlaps the second member;

the first end of the first member being connected to a second end of a second member of a circumferentially adjacent serpentine element of the ring;

the radially expandable rings being expandable under influence of a radially outwardly directed force, whereby the first and second members of each serpentine element move in circumferentially opposed directions to increase the circumferential length of each serpentine element; and

the stent being flexible substantially along its longitudinal axis when in its constricted state and being relatively more rigid along its longitudinal axis when expanded.

In general, the flexibility of the stent is inversely related to the number and length of the interconnecting members that join the ring sections. In order to maximize the flexibility in this invention, the length of the interconnecting member may be minimized practically to zero, allowing adjacent rings to be attached by at least two opposing peaks of their serpentine members to form one connection therebetween. The interconnecting member acts as a hinge between adjacent rings so the least number of hinges and the shortest length of the interconnecting member will enhance the flexibility and the range of movement of the ring elements of the stent during the constricted state. This flexibility of the stent makes it easy to adapt to the curved tortuous arterial pathway through which the stent is being passed.

It is a further object of the present invention to provide a stent which does not substantially change in length or at least does not reduce in length as the stent diameter expands during balloon inflation.

The stent may be deformed by the inflation of a balloon forming part of the catheter delivery system. The balloon expands the diameter by applying a radially-outwardly directed force. During the stent expansion, the joints or points of inflection deform so as to angularly separate the various members that constitute the stent. this will prevent any shortening in the longitudinal length after radial expansion of the stent.

It is further object of the present invention to supply the constricted stent with a minimum diameter to ease its passage for placement through a minimal diameter vascular point as well as to enable it to enter through narrow lumen of constricted body tubes. It is further object of the present invention to provide a stent geometry which allows both a greater expansion ratio for the stent and smaller stent diameter in order to fit into different diameter sizes of the body vessel. This present invention includes different arrangements of serpentine elements with their linear portions constructed to be aligned circumferentially or parallel to the longitudinal axis of the stent in the constricted state. The serpentine members are connected together by a variety of different connecting members to form rings which circumscribe the tubular contour of the stent. The stent is constructed to take advantage of opposing movements during expansion to minimize or eliminate longitudinal extension of the stent and to provide significant expansion in the circumference of the stent. The increase in the circumference results in an increase in the diameter of the stent after radial expansion. Depending on the amount of radial expansion needed, a combination of different numbers of serpentine elements and their connecting members that form the rings of the stent, as well as the manner in which the rings are interconnected, can be selected so as to provide a surgical stent which can be radially expanded to over four times its constricted diameter.

The stent is designed such that during expansion, local plastic deformation occurs only at the points of inflection distributed throughout the rings. Expansion is limited in proportion to the amount of expansion to ensure the resulting expanded stent is within material fracture limits and that adequate wall supporting structure is provided thereby. The stent is further designed such that it becomes more rigid when expanded and, thereby, provides greater resistance to radial collapse after deployment.

These and other objects and advantages of the present invention are described in the following description and illustrated by way of drawings.

Brief Description of the Drawings

Fig. 1A is a perspective view of a stent with the rear portion removed for clarity, constructed and operable according to the teachings of the present invention, shown in its constricted but highly flexible state prior to expansion; Fig. 1B is a perspective view of the embodiment of the stent of FIG. 1A in an expanded configuration;

Fig. 2A is a schematic drawing showing a flattened portion of the cylindrical contour of the stent embodiment of Fig. 1A; Fig. 2B is a schematic drawing of the flattened portion of the cylindrical contour of the stent as expanded;

Figs. 3A and 3B are cross-sectional views showing the stent of FIG. 1A in situ before and after expansion by a balloon forming part of its catheter delivery system;

Fig. 4A is a perspective view of an alternate embodiment of the stent with the rear portion removed for clarity, shown in its constricted but flexible state prior to expansion; Fig. 4B is a perspective view of the embodiment of the stent of Fig. 4A in an expanded configuration;

Fig. 5A is a schematic drawing showing a flattened portion of the cylindrical contour of the stent embodiment of Fig. 2A; Fig. 5B is a schematic drawing of the flattened portion of the cylindrical contour of the stent as expanded;

Figs. 6A, 6B and 6C are schematic drawings showing a portion of an individual ring of the embodiment of Fig. 2A and variants thereof;

Figs. 7A, 7B and 7C are schematic drawings showing a portion of an individual ring of the embodiment of Fig. 5A and variants thereof;

Figs. 8A, 8B, 8C and 8D are schematic drawings showing a portion of an individual ring and variants thereof based on the embodiment of Fig. 2A;

Figs. 9A, 9B, and 9C are schematic drawings showing a portion of an individual ring and variants thereof based on the embodiment of Fig. 5A;

Fig. 10 is a schematic drawing showing a flattened portion of the cylindrical contour of the stent constructed with rings as shown in Fig. 8A;

Fig. 11 is a schematic drawing showing a flattened portion of the cylindrical contour of the stent constructed with rings as shown in Fig. 9A;

Figs. 12A-12S are schematic drawings of exemplary configurations of extension elements and expansion segments which are usable in conjunction with this invention;

Figs. 13A and 13B are schematic drawings showing a portion of further variants of an individual ring based on the embodiment of Fig. 5A;

Figs. 13C and 13D are schematic drawings showing a portion of further variants of an individual ring based on the embodiment of Fig. 2A;

Fig. 14 is a schematic drawing showing another basic variant of an individual ring;

Figs. 15A and 15B are schematic drawings showing portions of individual rings based on the embodiments of Figs. 5A and 2A, respectively, but having alternative connection members between the serpentine elements;

Fig. 16 is a schematic drawing showing a portion of yet another individual ring based on the embodiment of Fig. 5A, but having a different medial member;

Fig. 17 is a schematic drawing showing a portion of yet another individual ring based on the embodiment of Fig. 5A, but having a different medial member;

Figs. 18A-18D are schematic drawings illustrating alternate embodiments of the interconnecting member disposed between pairs of adjacent rings;

Fig. 19 is a schematic drawing showing a flattened portion of the cylindrical contour of a stent constructed with rings as shown in Fig. 9A, but having an alternate manner for interconnecting the rings;

Fig. 20 is a schematic drawing showing a flattened portion of the cylindrical contour of a further stent constructed with rings as shown in Fig. 7A, but having an alternate manner for interconnecting the rings;

Fig. 21 is a schematic drawing showing a flattened portion of the cylindrical contour of another stent constructed with rings as shown in Fig. 7A, but having another alternate manner for interconnecting the rings;

Fig. 22 is a schematic drawing showing a flattened portion of the cylindrical contour of another embodiment of a stent made in accordance with the invention;

Fig. 23 is a schematic drawing showing a flattened portion of the cylindrical contour of a further embodiment of a stent made in accordance with the invention;

Fig. 24 is a schematic drawing showing a flattened portion of the cylindrical contour of yet another embodiment of a stent made in accordance with the invention;

Fig. 25 is a schematic drawing showing a flattened portion of the cylindrical contour of the stent of Fig. 24 as expanded;

Fig. 26 is a schematic drawing showing a flattened portion of the cylindrical contour of yet a further embodiment of a stent made in accordance with the invention; and

Fig. 27 is a schematic drawing showing a flattened portion of the cylindrical contour of another embodiment of a stent made in accordance with the invention.

Detailed Description of the Invention:

Fig. 1A illustrates a simple form of the invention in an expandable endovascular medical tubular stent 10 shown in its constricted state, i.e. prior to deployment and expansion. In general, the stent 10 comprises a plurality of interconnected radially expandable rings 12 arranged coaxially so as to form a generally tubular structure having a longitudinal axis 14. While three such ring elements 12a,12b,12c are shown in Fig. 1A, the stent of the present invention is operable with two or more such rings 12, the number of which is generally dependent on specific structure of the rings and how they are interconnected (as will be explained hereinbelow) as well as the desired length of the stent. The circular lines 13a,13b shown in phantom, represent in general the longitudinal boundaries of each ring 12 and are included to illustrate the cylindrical contour of the rings 12, particularly in the rear which has not been shown for purposes of clarity.

In general, the stent is manufactured as an integral structure but for the purposes of description, the stent is reduced effectively to a number of different elementary components.

As can be seen more specifically in Fig. 2A, each ring 12 of the stent 10 in the constricted state comprises a series of similar serpentine elements 16 connected together in a circular contour. Each serpentine element 16 comprises a pair of spaced-apart first and second members 18,20 which extend generally in the circumferential direction. A medial member 22 connects the first and second members 18, 20 such that they overlap in the circumferential direction. As

will be explained, the degree of circumferential overlap effects the extent of radial expandability of the stent 10.

Member 18 is considered to have first and second ends 18a, 18b and member 20 has first and second ends 20a,20b. Thus the medial member 22 generally connects the second end 18b of first member 18 with the first end 20a of the second member 20. The first end 18a of the first member 18 is connected to the second end 20b of the second member 20 of a circumferentially adjacent serpentine element 16 while the second end 20b of the second member 20 is connected to the first end of the other circumferentially adjacent serpentine element 16.

Medial member 22 is connected to the first and second members by plastically deformable joints 23, which may have a rounded shape as shown in Figs. 1A and 2A, form a rounded transition between the respective members.

In this embodiment, the serpentine element 16 is connected to circumferentially adjacent serpentine elements 16 by way of a connection member 24. Due to the specific configuration of the serpentine element 16 of stent 10, the connection member 24 is generally linear and is disposed substantially parallel to the longitudinal axis 14 when the stent 10 is in its constricted state as shown in Fig. 1A. The connection member 24 connects to the first end 18a of the first member 18 and to the second end 20b of the second member 20 of the circumferentially adjacent serpentine element 16 by plastically bendable joints 26, which form rounded corners as shown in Figs. 1A and 2A.

Each pair of adjacent rings 12a,12b; 12b,12c of stent 10 is interconnected by at least one interconnection member 28 disposed generally parallel with the longitudinal axis 14 of the stent 10 in its constricted state. Interconnecting members 28 bridge the space 30 between adjacent rings 12 and, in this embodiment, attach a connecting member 24 of one serpentine element 16 to the connecting member 24 of a corresponding serpentine element 16 of an adjacent ring 12. The interconnecting member 28 between rings 12b and 12c exists as shown in Figs. 2A and 2B, but is not shown in Figs. 1A and 1B because it is disposed in the rear portion which is not shown as aforesaid.

In general, the flexibility of the stent 10 with respect to its longitudinal axis 14 is inversely related to the number of the interconnecting members 28. Accordingly, it is preferred that the number of interconnections between adjacent rings be two. Depending on the actual structure of the individual components and material properties, the stent may have a single

interconnection between each pair of adjacent rings. More than two interconnections between adjacent rings starts to detract from the flexibility of the stent in its constricted state.

Referring now to Figs. 1B, 2B, 3A and 3B, the tubular stent 10 has an initial constricted diameter d (see Fig. 1A) which permits intra-luminal delivery of the stent into the lumen 32 of the body passageway or vessel 34 (see Fig. 3A) and is controllably deformed by application of an radially outwardly directed force from the interior of the stent 10, for example, by expandable balloon 36 of catheter 38, to an expanded diameter d'. The term "deformed" is used to indicate that the material from which tubular stent 10 is manufactured and in particular, the rings 12, is subjected to sufficient stress which is greater than the elastic limit of this material that portions thereof yield plastically. The radial expansion force results in circumferential expansion of the rings, effectively inducing a tensile stress in each of the serpentine elements 16. In general, the stent is designed through materials and structural considerations known to those skilled in the art such that the plastic deformation is caused to take place primarily in the joints or points of inflection due to bending stresses while the tensile forces incurred in the linear portions tend to be lower that the plastic yield strength of the material. Accordingly, upon radial expansion, the first and second members 18,20 of each serpentine element 16 will start to move in generally opposed circumferential directions as shown in Fig. 2B and plastic deformation starts to occur in the plastically deformable and/or bendable joints 23,26. The first and second members 18, 20, which are constrained by medial member 22, move angularly from a substantially circumferential direction as the medial member 22 moves angularly, thereby also causing the longitudinal distance (relative to the stent axis 14) between the second end 18b of the first member 18 and the first end 20a of the second member 20 to increase. The connection member 24 is also caused to move angularly as the first member 18 of one serpentine element 16 moves circumferentially away from the second member 20 of the circumferentially adjacent serpentine element 16. All of this results in expansion of the circumference of each ring 12a,12b,12c, and hence, an increase in the diameter d' of expanded stent 10' as shown in Fig. 1B. Referring to Fig. 2B, while the width w of each ring 12 increases to a width w' (between phantom lines 13a',13b' shown in Fig. 1B) the overall length l of the stent either increases slightly to length l' or remains substantially the same due to the presence of the interconnecting members 28, which, by moving angularly as the connecting members 24 move angularly, operate to decrease the length of the spaces 30 between the rings 12, thereby offsetting the increase in the length of the stent due to the increase in width of the rings 12. The widening of the rings 12 coupled

with the decrease in the longitudinal spacing 30 between the rings 12 results in the stent 10 providing more comprehensive support to the inner wall 40 of the passageway 34 over practically the entire length of the expanded stent 10'.

In general, the idea is to permit substantial radial expansion but not to the extent that the plurality of serpentine elements 16 and connecting members 24 become overly straightened, i.e. relatively circular, because such a resulting structure would generally not provide adequate support along the entire inner surface of the passageway 34. In addition, the more each ring 12 is expanded, the greater the risk of failure or breakage by exceeding the plastic limit of the material at one or more of the joints 23,26 or even exceeding the tensile strength of the linear members, leading to plastic deformation thereof and possibly ultimate failure. Accordingly, it is preferred that the rings 12 are caused to expand radially to a point whereabout the width of the ring 12 is substantially maximized or where the medial members 22 are disposed generally parallel to the longitudinal axis 14 of the stent. This point can be ascertained in terms of the diameter d' either empirically or through analysis of the geometry of the ring and provided to the user by way of an accompanying specifications sheet.

Alternatively, the joints 23,26 may engineered to take advantage of work-hardening properties of certain materials so as to work-harden in proportion to the amount of plastic deformation. This property can be employed to limit the amount of plastic deformation and, hence, the extent to which the rings 12 will expand so as to ensure adequate wall support all along the section of the passageway in which the stent is deployed. In general, the inflection points (joints) are designed to "open", i.e. to increase the angle between the joined members/elements, to a limited extent. Those joints that have an initial included angle α of approximately 0°, i.e. double-back joints such as deformable joint 23 shown in Fig. 2A, are not intended to expand angularly to 180° (straighten), but rather are preferably limited to a range of less than about 150°, and more preferably, to a range of about 90°or less. Those joints having an initial included angle β of approximately 90°, such as bendable joint 26 in Fig. 2A, while angularly expandable to about 180°, are preferably limited to a range of about 90° to 150°. Such limitations will ensure a significant normal component is maintained between the elements that the joint separates for providing a more comprehensive supporting structure to the passageway wall when the stent is expanded. In addition, by attaining a significant normal component between the elements that the joint separates, the stent 10' when expanded will have less flexibility than while it was in its constricted state 10, thereby rendering the stent 10' less prone to collapse after deployment. If advantage is taken of the

work hardening property to limit expansion, then the resulting expanded stent 10′ will be even less flexible and less subject to plastic deformation and, thus, is more capable of resisting the radially inwardly directed force applied by the vessel wall 40 on the stent 10′ after deployment.

Preferably, the distance between adjacent rings, and hence the length of the interconnecting members 28, is kept to a minimum to ensure a maximum amount of support along the inner surface of the passageway yet sufficiently spaced-apart to enable the rings to expand longitudinally without interference from the expansion of an adjacent ring.

The tubular stent 10 is preferably fabricated from biocompatible, low memory, more plastic than elastic material to permit the stent 10 to be expanded and deformed from the configuration shown in Figs. 1A and 2A to the configuration shown in Figs. 2A and 2B, yet sufficiently rigid to permit the tubular stent 10 to retain its expanded and deformed configuration with enlarged diameter d′ and also to resist radial collapse.

Typically, stents in accordance with the teachings herein may be expanded up to about four times their original constricted diameters yet still have desirable properties of good axial flexibility in the constricted state and resistance to radial collapse and comprehensive wall support in the expanded state. Accordingly, stents may be provided for example in nominal diameters d of about 1mm, 1.5mm, and 2mm which, depending on the specific structure, may be expanded to 4mm, 6mm or 8mm, respectively, which should enable a minimum number of stents to be employed in most situations. It should be borne in mind that the stents of the present invention are operable over their entire range because they deform substantially continuously under application of an radially outwardly directed force. Upon removal of the force, deformation halts and the stent remains sufficiently rigid to withstand the radial force of the wall which it supports.

Suitable materials for the fabrication of the tubular stent 10 would include silver, tantalum, stainless steel (316 L), gold, titanium, NiTi alloy or any suitable plastic materials such as thermoplastic polymers. Any medically-suitable metal having work hardening properties which is capable of yielding plastically under the typical forces of a balloon catheter could also be employed. Alternatively, the stent 10 may be made of a radioactive material or irradiated with a radioactive isotope. The radioactive isotope may be a beta particle emitting radioisotope. By using a stent made of the radioactive material, cancer cells in and around the stent can be deactivated or killed. Alternatively, the stent can be coated with materials that prevent cell overgrowth. The stent may be coated with an anticoagulating medication

substance, such as heparin, and/or a bioabsorbable material. Accordingly, when the stent is used in a blood vessel, blood clotting can be prevented. Also, the stent may have pores, indentations or a roughened surface capable of absorbing or retaining a drug therein/thereon for slowly releasing the same over time. Thus, when the stent with a drug is implanted in the body lumen, the drug can slowly released in the body lumen. To enhance visibility of the stent when viewed by various different medical imaging devices, the end rings 12a,12c can be formed from a radio-opaque material, such as gold, silver or platinum, which allows both ends of the stent to be clearly visible through a medical imaging device during or after implantation of the stent within a body lumen of the patient.

The stent 10 is preferably formed by laser cutting technology wherein the pattern is cut into a cylindrical section of the appropriate material. Other suitable methods may be used, for example, the stent can be formed by an etching technique. Namely, a pattern of the rings 12a,12b,12c and the interconnecting members 28 are coated on a cylindrical metal member, which is etched in an acid solution. Then, un-coated portions are removed.

Figs. 4A and 5A illustrate an alternative tubular stent 50 which is similar to the stent 10, in that it comprises a plurality of interconnected rings 52, each of which consists of a plurality of similar serpentine elements 16,16a joined together in a circular band. The circular lines 53a,53b shown in phantom in Fig. 4A, represent in general the longitudinal boundaries of each ring 52 and are included to illustrate the cylindrical contour of the rings 52, particularly in the rear which has not been shown for purposes of clarity.

Each of the serpentine elements 16,16a comprises a pair of spaced-apart first and second members 18,20 which extend generally in the circumferential direction. A medial member 22 connects the first member 18 to the second member 20 through plastically deformable joints 23 such that the first and second members 18,20 overlap in the circumferential direction. In this embodiment, however, each serpentine element 16 is the reverse with respect to its circumferentially adjacent serpentine elements 16a, necessitating an even number of serpentine elements 16,16a for constituting each ring 52. Accordingly, the first member 18 of one serpentine element 16 is connected to the first member 18 of a circumferentially adjacent serpentine element 16a while the second member 20 is connected to the second member of the other circumferentially adjacent serpentine element 16a. For the purposes of description, a connection member 24 can be considered to be provided between adjacent first members 18,18 and adjacent second members 20,20. At least one, but preferably a pair of diametrically

opposed, interconnecting members 28 are provided between each pair of adjacent rings 52a,52b; 52b,52c.

Upon application of a radially outwardly directed force from inside the constricted stent 50, each serpentine element 16,16a is essentially placed under tension, causing the first and second members 18,20 to move in circumferentially opposite directions, as seen in Figs. 4B and 5B. Deformation takes place in the plastically deformable joints 23 as the medial member 22 moves angularly, thereby, increasing the width of the rings 52 from width w to width w'.

If the interconnecting members 28 connect the first members 18 of a pair of circumferentially adjacent serpentine elements 16,16a to the first members 18 of a pair of circumferentially adjacent serpentine elements 16,16a of an adjacent ring 52 or, as shown in Fig. 5A, if the interconnecting elements 28 connect the second members 20 of a pair of circumferentially adjacent serpentine elements 16,16a to the second members 20 of a pair of circumferentially adjacent serpentine elements 16,16a of an adjacent ring 52, then the amount of longitudinal extension of the stent 50' from length l to l' will be limited to the amount of longitudinal extension from width w to w' of a single ring 52.

Again, the objective is not to expand the stent 50 to its fullest extent whereat the serpentine elements are substantially straightened, but rather to such an extent whereby the desired diameter d' of the stent can be achieved while permitting significant support of the vessel wall 40 all over its cylindrical inner surface by having a substantive framework of the elements which constitute the expanded stent in the circumferential and longitudinal directions or as components of those directions. In general, the inflection points (joints) are designed to "open" to a limited extent. Those joints that have an initial included angle α of approximately 0°, i.e. double-back joints such as deformable joint 23 shown in Fig. 2A, are not intended to expand radially to 180° (straighten), but rather are preferably limited to a range of less than about 150°, and more preferably, to a range of about 90° or less. Such limitations will ensure a significant normal component is maintained between the elements that the joint separates for providing a more comprehensive supporting structure to the passageway wall when the stent is expanded.

As previously mentioned, the stent is designed with shape, material property and force considerations in mind such that the majority, if not the entirety, of the plastic deformation takes place in the plastically deformable joints 23 and in the plastically bendable joints 26, if provided. Preferably, the joints 23,26 may be engineered to take advantage of work-hardening

properties of certain materials so as to work-harden in proportion to the amount of plastic deformation. This property can be employed to limit the amount of plastic deformation and, hence, the extent to which the rings 12 will expand so as to ensure adequate wall support all along the section of the passageway in which the stent is deployed. Accordingly, the joints 23,26 may be shaped in a variety of ways to achieve these engineering objectives and/or for manufacturability. Exemplary configurations of joints are shown in Figs. 6A-6C and 7A-7C which illustrate flattened projections of individual ring segments in their constricted state. Figs. 6A-6C show various exemplary rings 12,112,212 of type shown in Fig. 2A wherein each serpentine element 16,116,216 is connected to an adjacent serpentine element 16,116,216 by connecting members 24,124,224, respectively. More specifically, the ring 12 of Fig. 6A is of the type as illustrated in Fig. 2A having semi-circular or rounded plastically deformable joints 23 connecting the medial member 22 with each of the first and second circumferentially-extending members 18,20 and rounded plastically bendable joints 26 by way of which the connecting member 24 is connected to the respective first and second members 18,20 of the adjacent serpentine elements 16.

Fig. 6B shows a ring 112 comprising a series of serpentine elements 116 including first and second members 118,120 connected in overlapping circumferential fashion by way of medial member 122. In this arrangement, the joints 123,126 are angular with plastically deformable join 123 being generally straight so as to form a double right-angled connection between the medial member 122 and each first and second member 118,120. Similarly, the plastically bendable joints 126 form generally right-angled connections between the connection member 126 and its respective first and second members 118,120.

Fig. 6C illustrates a ring 212 similar to the ring 12 of Fig. 6A except that the plastically deformable joints 223 of the serpentine element 216 disposed between the medial member 222 and each of the first and second members 218,220 form a bulbous connection which is greater than 180°. This form of connection induces more consistent plastic deformation throughout the entirety of the joint.

Figs. 7A-7C show various exemplary rings 52,152,252 of type shown in Fig. 5A wherein each serpentine element 16,116,216 is reversed with respect to its adjacent serpentine element 16a,116a,216a. In Fig. 7A, the plastically deformable joints 23 connecting the medial member 22 with the first and second members 18,20 are rounded or semi-circular. In Fig. 7B, the plastically deformable joints 123 connecting the medial member 122 with the first and second

members 118,120 are generally straight so as to form a double right-angled connection. In Fig. 7C, the plastically deformable joints 223 connecting the medial member 222 with the first and second members 218,220 form a bulbous connection similar to that shown in Fig. 6C.

In order to increase the stent's capability to expand radially, it would be desirable to provide the first and second members with the ability to extend generally lengthwise when placed under tension. This may be accomplished by means of an extension elements such, as for example, as are illustrated in Figs. 8A-8D and 9A-9C. Fig. 8A shows a ring 60, similar to the ring 12 of Fig. 6A, wherein rounded U-shaped extension elements 61 are provided intermediate each first and second member 62,63. Extension element 61 is designed to deform plastically at its joint 64a and at the member interfaces 64b. Fig. 8B shows a ring 65, similar to the ring 112 of Fig. 6B, wherein rectangularly U-shaped extension elements 66 are provided intermediate each first and second member 67,68. Extension element 66 is designed to deform plastically at its double right-angled joint 69a and at the member interfaces 69b. Fig. 8C shows a ring 70, similar to the ring 212 of Fig. 6C, wherein bulbous U-shaped extension elements 71 are provided intermediate each first and second member 72,73. Extension element 71 is designed to deform plastically at its bulbous joint 74a and at the member interfaces 74b. Fig. 8D shows a ring 75, similar to the ring 112 of Fig. 6B, wherein V-shaped extension elements 76 are provided intermediate each first and second member 77,78. Extension element 76 is designed to deform plastically at its angled joint 79a and at the member interfaces 79b. The addition of an extension element not only enhances the stent's capability to expand radially, but also serves to increase the amount of material in the stent which, when expanded, will provide more comprehensive support to the wall 40 of the body passageway 34 and will serve to better resist radial collapse after expansion.

Alternately, the capability to radially expand without detracting overly from the capability to support the wall 40 relatively comprehensively may also be provided through the use of an expansion segment within the connecting member between circumferentially adjacent serpentine elements. As shown in Fig. 8D, an expansion segment 80 is provided intermediate the connecting member 82 connecting the first member 77 of one serpentine element with the second member 78 of its circumferentially adjacent serpentine element. As shown, expansion segment 80 is V-shaped, but could be any of a variety of shapes (as will be detailed hereinbelow) which would enable the connecting element to expand lengthwise when placed under tension. In this regard, expansion element 80 is designed to deform plastically at its angled joint 84a and at the connecting member interfaces 84b. Like the extension elements

which may be provided in the first and second elements, the addition of an expansion segment not only enhances the stent's capability to expand radially, but also serves to increase the amount of material in the stent which, when expanded, will provide more comprehensive support to the wall 40 of the body passageway 34 and will serve to better resist radial collapse after expansion.

As described in connection with Figs. 5A and 5B, a connection member 24 can be considered to be provided between adjacent first members 18,18 and adjacent second members 20,20 of the ring arrangement where each serpentine element 16 is the reverse of its circumferentially adjacent serpentine elements 16a. In general, when the connection element 24 is entirely in-line between the first members or second members, there is no plastic deformation as the segments 18,24,18 or 20,24,20 are designed to withstand the tensile stress induced therein during expansion of the stent without plastic deformation. However, as was the case with the Fig. 8D embodiment, it is possible to increase the stent's capability to expand by including an expansion segment in the connecting member as is exemplified in Figs. 9A-9C. Fig. 9A illustrates a ring 90, similar to the ring shown in Fig. 7A, including a rounded, U-shaped expansion segment 91 disposed intermediate each connecting member 24 and hence between adjacent first members 18,18 of circumferentially adjacent serpentine elements 16,16a and between adjacent second members 20,20 of circumferentially adjacent serpentine elements 16a,16. As is the case with all of the remainder of the stent structure, the expansion segment is designed to deform or bend plastically at its points of inflection, i.e. at its joints. Fig. 9B shows an alternate ring 93 arrangement, similar to the ring 152 of Fig. 7B, wherein rectangularly U-shaped expansion segments are disposed intermediate the connecting member 124. Fig. 9C shows yet another ring 96 arrangement, similar to the ring 252 of Fig. 7C, wherein bulbous U-shaped expansion segments 97 are provided intermediate the connecting member 224. In this case, the expansion segment 97 includes over-rounded corners 98.

As with the rings 12 of Fig. 2A and the rings 52 of Fig. 5A, a plurality of rings 60,65,70,75 of Figs. 8A-8D or the rings 90,93,96 of Figs. 9A-9C are interconnected to form a generally tubular stent. By way of example, a plurality of rings 60 of Fig. 8A are arranged coaxially to form a stent shown in its constricted state 100 in Fig. 10. One or more interconnecting members 28 serve to interconnect each pair of adjacent rings 60a,60b; 60b,60c and, more specifically, to attach the connecting member 24 between a pair of circumferentially adjacent serpentine elements 16 to a connecting member 24 between a longitudinally adjacent pair of circumferentially adjacent serpentine members 16. Similarly, Fig. 11 shows a stent 102 in its

constricted state comprised of a plurality of rings 90a,90b,90c of the type of ring 90 shown in Fig. 9A. Each pair of adjacent rings 90a,90b; 90b,90c are interconnected by at least one interconnecting member 28 disposed intermediate expansion segment 91 of one connecting member 24 and the expansion segment 91 of the connecting member 24 between an longitudinally adjacent pair of circumferentially adjacent serpentine elements 16,16a.

As mentioned above, the extension elements and expansion segments can take the form of a variety of configurations. Figs. 12A-12S illustrate exemplary configurations 99a-99s, respectively, which may be utilized to achieve the desired lengthwise extension or expansion of the element in which they are implemented. The shapes of the elements or segments of Figs. 12A to 12D are, respectively: rectangular U-shaped; V-shaped; rounded U-shaped; and bulbous U-shaped, each of which extends transversely relative to the end-to-end relationship element or segment. In Fig. 12E, two transversely-extending but alternating, rectangular U-shapes are shown. Fig. 12F shows two transversely-extending but alternating V-shapes. Fig. 12G also shows two transversely-extending but alternating V-shapes which could equally be characterized as a longitudinally-extending Z-shape. Fig. 12H shows two transversely-alternating rounded U-shapes which could equally be characterized as a longitudinally-extending S-shape while Fig. 12I shows two transversely-alternating bulbous U-shapes. Fig. 12J shows a plurality of transversely-extending, rectangular U-shapes, Fig. 12K shows a plurality of transversely-extending V-shapes, and Fig. 12L shows a plurality of transversely-extending rounded U-shapes which could equally be characterized as a longitudinally-extending double S-shape. In this regard, any number of singular elements may be combined to form a flexuous element. Fig. 12M shows a plurality of transversely-extending alternating bulbous U-shapes. The expansion element 99n of Fig. 12N is S-shaped, but unlike the S-shaped expansion elements 99h or 99l whose respective ends 99h',99l' are in line, the ends 99n' of expansion element 99n are offset with respect to one another. Similarly in Fig. 12O, the ends 99o' of transversely alternating, rectangular U-shaped expansion element 99o are offset as compared with the ends 99j' of element 99j shown in Fig. 12J. Fig. 12P shows a plurality of rectangular U-shapes which alternate transversely. Fig. 12Q shows a plurality of V-shapes which alternate transversely. Fig. 12R shows a plurality of rounded U-shapes which alternate transversely and Fig. 12S shows a plurality of bulbous U-shapes which alternate transversely. The elements/segments 99a-99s shown in Figs. 12A-12S, many of which have sinusoidal derivations, are intended to exemplify the variety of shapes and configurations and by no means are meant to be limiting. In common with all of the elements/segments 99a-99s

is that plastic deformation due to bending occurs at their points of inflection so that included angles open under tension applied between the ends. Included angles which are approximately 0° are limited to expand to less than 180°, preferably less than 150° and even more preferably to about 90° or less. Included angles which are less than 90°, i.e. the acute-angled V-shapes, are also limited to expand to less than 180°, preferably less than 150° and even more preferably to about 90° or less.

The elements 99a-99s shown in Figs. 12A-12S are not limited for use in association with the first and second members 18,20 and connecting members 24, but may also be used in other elements where expansion or extension is desired, such as in medial member 22 and/or in interconnecting member 28.

To illustrate further the manner in which the extension elements and expansion segments 99a-99r could be implemented in a stent according to the invention, reference is made to Figs. 13A-13D. Fig. 13A shows a ring 130, similar to ring 90 of Fig. 9A, in which an expansion segment 132 is included as part of the connecting member 24 disposed between adjacent first members 18,18 of circumferentially adjacent serpentine elements 16a,16 and as part of the connecting member 24 disposed between adjacent second members 20,20 of circumferentially adjacent serpentine members 16,16a. In this case, the expansion segment is of the form of segment 99l shown in Fig. 12L. Fig. 13B shows a ring 140 similar to the ring 130 of Fig. 13A, with the exception that expansion segment 142 is of the form of segment 99r as shown in Fig. 12R. As can be seen in both Figs, 13A and 13B, the medial member 22 connects first member 18 to second member 20 in at least partially circumferentially overlapping fashion.

Fig. 13C shows a ring 155, similar to ring 60 of Fig. 8A, in which an extension element 157 is disposed generally centrally in each first and second member 18,20. Extension element 157 is of the form of segment 99l as shown in Fig. 12L. Fig, 13D shows a ring 160, similar to the ring 150 of Fig. 13C, with the exception that the extension element 162 disposed generally centrally in each first and second member 18,20 is provided with an additional undulation (as compared with the extension element 157) which not only provides enhanced radial expandability of the ring 160, but also adds to the amount of material available for wall support.

It will be appreciated that with the variety of components shown and described that any combination thereof could be used to construct a stent in accordance with the invention. For example, it is not necessary that the series of serpentine elements be the same or alternating

as shown in Figs. 6A or 7A. The ring could be comprised of a plurality of serpentine elements arranged generally randomly or in another sequence, such as in ring 170 shown in Fig. 14. Ring 170 comprises a pair of similarly oriented serpentine elements 171 between which is interposed a reversely oriented serpentine element 172. It will also be appreciated that the extension element used for example in the first member could be different from that used in the second member.

Figs. 15A and 15B show alternate arrangements of the connecting members disposed between adjacent serpentine elements which generally expand as opposed to extend. In Fig. 15A, alternating connecting members 177,178 having U-shaped expansion segments are disposed between circumferentially alternating serpentine members 176,177 of ring 175. In Fig. 15B, connecting members 182 having S-shaped expansion segments are disposed between circumferentially similar serpentine members 181 of ring 180.

It will also be appreciated that the expansion/extension principles described and illustrated herein can be applied to both the medial members and the interconnecting members and that for this purpose, the shapes shown in Figs. 12A-12S as well as others, could be utilized. For example, Fig. 16 illustrates a ring 185 which is similar in form to ring shown in Fig. 7A, having circumferentially alternating serpentine elements 186,186a comprised of circumferentially extending first and second members 187,188. Medial member 189 is connected between the first and second members 187,188 such that they at least partially circumferentially overlap. In this case, the medial member 189 consists of an N-shaped (alternating U-shaped) arrangement in which the linear portions thereof extend generally in the circumferential direction. In Fig. 17, ring 190 is comprised of a series of alternately-oriented serpentine elements 191,191a, each consisting of circumferentially extending first and second members 192,193. Medial member 194 is connected between the first and second members 192,193 such that they at least partially circumferentially overlap. In this case, the medial member 194 consists of an S-shaped (or alternating U-shaped) arrangement, in which the linear portions are disposed generally parallel to the longitudinal axis 14 of the stent in its constricted state.

It will also be appreciated the manner in which the rings are interconnected can also be effected in a number of ways. In general, the interconnection can take the form of an interconnecting member as described above, with or without the capability for extension/expansion, or it can be as simple as integrally forming one or more portions of one

ring with that of an adjacent ring. Figs. 18A-18D show schematically the use of extendable sections in the interconnecting member disposed between adjacent pairs of rings 195. In Fig. 18A, a U-shaped extendable section 196, similar to the element 99c shown in Fig. 12C, is disposed transversely of the interconnecting member. A second U-shaped extendable section 196a is disposed in the opposite interconnecting member in such a manner that if the stent as shown in Fig. 18A were rotated 180° about its longitudinal axis, the U-shaped extendable section 196a would appear in the same orientation as the U-shaped extendable section 196 as shown in Fig. 18A. In Fig. 18B, alternating V-shaped extendable section 197, similar to the element 99f shown in Fig. 12F, is included in one interconnecting member. An alternating V-shaped extendable section 197a is disposed in the opposite interconnecting member in such a manner that if the stent as shown in Fig. 18B were rotated 180° about its longitudinal axis, the alternating V-shaped extendable section 197a would appear in an upside-down orientation as compared with the alternating V-shaped extendable section 197 as shown in Fig. 18A. Both of the interconnecting members 196,197 illustrated in Figs. 18A and 18B are of such a configuration that their ends are disposed along a line which is generally coaxial with respect to the longitudinal axis of the stent. However, depending on the actual shape of the extendable section employed in the interconnecting member, the ends thereof could be circumferentially offset, such as is shown in Fig. 18C. In this variant, a longitudinally extending S-shaped extendable section 198, similar to element 99n of Fig. 12N, is disposed between the ends of each interconnecting member. Due to the configuration of S-shaped member 198, the ends of the interconnecting member are not disposed in a line which is generally coaxial with respect to the longitudinal axis of the stent, but rather, they are circumferentially offset. In Fig. 18A, it can be seen that the interconnecting member 196 interconnects proximal portions 195b,195c of adjacent rings 195. It will be appreciated that the interconnecting member may be used to interconnect proximal (195b,195c) or distal (195a,195d) portions of adjacent rings 195 or, as shown in Fig. 18D, to connect a proximal portion 195a of one ring at a first end 199a with a distal portion 195d of the other ring 195 at a second end 199b. This manner of interconnection is also illustrated in Fig. 11. Transversely extending, rectangularly U-shaped extendable section 199, similar to element 99a of Fig. 12A, is disposed in the interconnecting member of Fig. 18D.

As indicated above, the interconnecting member can be as simple as integrally forming one or more portions of one ring with that of an adjacent ring. For example, Fig. 19 shows a section of stent 200 comprised of a plurality of alternating rings 201,202 of the type shown in

Fig. 9A. At selective locations 203, the U-shaped connecting member 204a of one ring 201 is integrally formed, fused or otherwise attached to the connecting member 204b of an adjacent ring 202. Fig. 20 illustrates a portion of a stent 205 comprised of alternating rings 206,207 of the type shown in Fig. 7A. In this arrangement, relatively short interconnecting members 208 interconnect adjacent rings 206,207 at selected locations. Preferably, there are not more than two interconnecting members provided per pair of adjacent rings 206,207. The short length of the interconnecting members 208 enhance the flexibility of the stent while in constricted state to facilitate easy maneuver through tortuous arterial pathway.

Fig. 21 illustrates a section of a stent 230 comprised of alternating rings 232,234 of the type shown in Fig. 7A. In this case, the interconnection is effected by lengthwise integrally forming selected adjacent circumferentially extending first/second members 236. In Fig. 22, a section of a stent 240 is shown comprising a plurality of alternating adjacent rings 241,242, each consisting of a plurality of serpentine elements 243 each having circumferentially extending first and second members 244,245 connected by an undulating or flexuous medial member 246. While the undulating characteristic of the medial member 246 can enhance expansion in the tensile direction, even where the stent is not expanded to such an extent so as to take advantage of its expansion capability, the undulating characteristic provides substantial surface area coverage which results in more comprehensive wall support as compared with a linear counterpart.

An expandable, U-shaped connection member 247 connects some of the serpentine elements 243 circumferentially while a linear connecting member 248 connects others. At selected locations 249, the connecting member 247a of one ring 271 is integrally formed, fused or otherwise attached, to a connecting member 247b of adjacent ring 272. This arrangement has been found to provide excellent axial flexibility of the stent. Because of the substantive usage of expansion/extension elements and the compactness thereof, this stent has a relatively great range of radial expansion and substantial wall support.

Fig. 23 shows a section of a stent 255 comprising a plurality of alternating rings 256,257, each consisting of a series of similar serpentine elements 258 connected circumferentially by linear connecting member 259. Each serpentine element 258 comprises circumferentially extending first and second members 260 connected by way of undulating medial member 262. Adjacent rings 256,257 are interconnected at selected locations by interconnecting members 263. As can be seen, the section of the stent 255 has a relatively high, initial surface density (ratio of

material area to area of gaps/spaces) which will result in reasonably good surface density after expansion since the extent to which the rings will expand will be limited as mentioned above in conjunction with the description of Figs. 2B and 5B.

A variation of the stent 240 of Fig. 22 is illustrated at 270 in Fig. 24, comprising a plurality of alternating rings 271,272. Each ring 271,272 consists of a plurality of alternating serpentine elements 278,278a connected by alternatingly-oriented U-shaped connecting members 276. The rings 271,272 are positioned such that adjacent U-shaped connecting members either have adjacent apexes or adjacent openings (i.e. opposed apexes). Relatively short interconnecting members 279 are provided at selected locations between the apex of connecting member 276a of one ring 271 and the adjacent apex of a connecting member 276b of an adjacent ring 272. In accordance with the teachings of the invention, interconnecting member 279 could comprise a linear element as shown or could comprise an expansion element of the type shown in Figs. 12A-12S. The configuration of stent 270, which represents the best mode, has been found to provide an exceptional working range respecting expansion (on the order of four times the original diameter), without significantly compromising the strength of the stent when expanded or detracting overly from the extent to which the stent can provide coverage and support throughout the entire inner surface of the passageway wall. Just as important, however, is the fact that the configuration of stent 270 results in a high axial flexibility when in its constricted state, which does not only prove advantageous when navigating the tortuous paths of some arterial pathways, but also permits the stent to be provided in relatively smaller initial diameters thereby permitting easier access and reducing the risk of any damage. A further advantage of this particular configuration is that radial expansion results in substantially little if any longitudinal extension or contraction which facilitates positioning of the stent in the passageway. Fig. 25 shows schematically the initial expansion of the stent 270 of Fig. 24. As can be seen, a relatively small opening up (approximately 30°) of the angle α' from α, which was substantially 0° as shown in Fig. 24, results in an almost two-fold increase in the circumference of the stent 270'. It will be appreciated that while only connecting members 276 open up and serpentine elements 278,278a move angularly upon initial expansion, as the generally elongate serpentine elements 278,278a become aligned more circumferentially (i.e. the first and second members 280,281 move angularly towards a parallel orientation with respect to the axis of the stent), the tensile stress on the serpentine elements 278,278a will induce plastic deformation at the rounded joints 283 and, thus, expansion of the serpentine elements 278,278a in a generally circumferential direction and, hence, even greater

expandability. The stent of Fig. 25 can easily expand to four times its initial diameter while still maintaining comprehensive wall support and its resistance to radial collapse.

Fig. 26 shows a stent 310 which is similar to the stent 270 of Fig. 24, comprising a plurality of alternating rings 311,312. Each ring 311,312 consists of a plurality of alternating serpentine elements 318 connected by alternatingly-oriented U-shaped connecting members 316. Whereas the stent 270 of Fig. 24 utilizes a relatively short interconnecting member 279 between selected portions of adjacent rings, the stent 310 of Fig. 26 includes in its interconnecting member 319 an extendable section 399. The extendable section 399 provides additional flexibility to the stent along its longitudinal axis when in its constricted shape. While extendable section 399 is shown as being U-shaped, it will be appreciated that any shape, such as those illustrated in Figs. 12A-12S could be employed.

Fig. 27 shows yet another embodiment of a stent 320 comprising a plurality of alternating rings 321,322 of a form similar to the rings 271,272 of the stent 270 of Fig. 24, except that the medial member 323 of stent 320 includes one less undulation (i.e. the medial member 323 is single S-shaped) and that the space between the legs of the U-shaped connecting member 326 is greater. The rings 321,322 are positioned such that adjacent U-shaped connecting members either have opposed or adjacent apexes. Whereas in the stent 270 of Fig. 24 the interconnecting member 279 bridges adjacent apexes, the at least one interconnecting member 329 between each pair of adjacent rings 321,322 of stent 320 connects opposed apexes. Such an arrangement ensures no longitudinal contraction of the stent will occur upon radial expansion.

For exemplary purposes, the stents illustrated herein have been shown as comprising three or four interconnected rings. However, due to the minute sizes of the elements involved, typical stents would usually comprise several more rings. To give an idea of the dimensions involved, a typical stent for use in coronary arteries such as is shown in Fig 24, might have an unconstricted diameter on the order of 1.2mm. The width of each ring would be on the order of about 1mm. Accordingly, there would be 15 or so rings on a stent which is initially 15mm in length. The circumferentially adjoining combination of a connecting member 276, a serpentine element 278a, another connecting member 276 and a serpentine element 278 repeats about every 1.25mm circumferentially. Accordingly, for a 1.2mm diameter stent, three serpentine elements 278, three serpentine elements 378a and six connecting members 276 would form each ring 271,272. The gaps between parallel portions of linear members, such

as the struts forming the legs of U-shaped connecting members 276 are on the order of about 0.05mm. The width of the material which forms the various elements, members, joints, etc., while variable to achieve the plastic deformation at the points of inflection, are generally also on the order of about 0.05mm. The thickness of the material, i.e the stent's tubular wall thickness is on the order of about 0.05-0.2mm. The cross-sectional configuration of the material can be varied, although it will likely depend upon the manner in which the stent is manufactured. For, example, using laser cutting on a piece of tubular material, the resulting members which are disposed in the circumferential direction will have roughly rectangular cross-sections while the members generally parallel to the longitudinal axis will likely have a slightly trapezoidal cross-section if the axis of the laser intersects the axis of the tubular material. A more rectangular cross-section would be obtainable with an appropriate offset of the laser's axis.

Having described this invention with regard to specific embodiments, it is to be understood that the invention has been described with respect to a limited number of embodiments. It will be appreciated that many variations, modifications and other applications of the invention may be made. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

I CLAIM:

1. An endovascular tubular stent expandable between a first, constricted state and a second state of greater expanded diameter; said stent comprising in its constricted state:

a plurality of interconnected radially expandable rings each formed of a plurality of circumferentially extensible serpentine elements, each circumferentially extensible serpentine element comprising:

first and second generally circumferentially-extending members each having respective first and second ends, said first and second members being spaced-apart in the axial direction of the stent; and

a medial member connecting the second end of said first member with the first end of said second member such that at least a portion of said first member circumferentially overlaps said second member;

said first end of said first member being connected to a second end of a second member of a circumferentially adjacent serpentine element of said ring;

said radially expandable rings being expandable under influence of a radially outwardly directed force, whereby the first and second members of each serpentine element move in circumferentially opposed directions to increase the circumferential length of each serpentine element; and

said stent being flexible substantially along its longitudinal axis when in its constricted state and being relatively more rigid along its longitudinal axis when expanded.

2. The stent of claim 1, wherein plastically deformable joints form connections between an end of the medial member and said second end of said first member and between another end of said medial member and said first end of said second member.

3. The stent of claim 2, wherein adjacent pairs of said radially expandable rings are interconnected such that expansion of said radially expandable rings results in substantially no reduction of the length of the stent in its expanded state from its length in its constricted state.

4. The stent of claim 2, wherein said plastically deformable joints form a rounded transition between said first member and said medial member and between said second member and said medial member.

5. The stent of claim 2, wherein said plastically deformable joints form a semi-circular transition between said first member and said medial member and between said second member and said medial member.

6. The stent of claim 2, wherein said plastically deformable joints form bulbous transition between said first member and said medial member and between said second member and said medial member.

7. The stent of claim 2, wherein said plastically deformable joints are generally straight so as to form double right angles between said first member and said medial member and between said second member and said medial member.

8. The stent of claim 2, wherein said plastically deformable joints form an included angle between said first member and said medial member and between said second member and said medial member of approximately 0°.

9. The stent of claim 2, wherein said plastically deformable joints form an included angle between said first member and said medial member and between said second member and said medial member of approximately 90°.

10. The stent of claim 2, wherein expansion of said rings is limited in proportion to the amount of expansion.

11. The stent of claim 10, wherein said stent is fabricated from a work-hardenable material, and wherein said plastically deformable joints work-harden in proportion to the amount of plastic deformation.

12. The stent of claim 11, wherein said plastically deformable joints work-harden to limit angular expansion between said first member and said medial member and between said second member and said medial member so that said medial member has a generally normal component relative to said first and second members.

13. The stent of claim 12, wherein said plastically deformable joints form an included angle between said first member and said medial member and between said second member and said medial member of approximately 0° when in said constricted state, and wherein said angular expansion is limited to less than 180°.

14. The stent of claim 13, wherein said angular expansion is limited to less than 150°.

15. The stent of claim 14, wherein said angular expansion is limited to about 90° or less.

16. The stent of claim 12, wherein said plastically deformable joints form an included angle between said first member and said medial member and between said second member and said medial member of approximately 90° when in said constricted state, and wherein said angular expansion is limited so that said included angle remains less than 180°.

17. The stent of claim 16, wherein said angular expansion is limited so that said included angle remains less than about 150°.

18. The stent of claim 2, wherein said first and second members have a substantially circumferentially linear shape.

19. The stent of claim 2, wherein said first and second members are lengthwise extensible.

20. The stent of claim 19, wherein said first and second members each include at least one extension element.

21. The stent of claim 20, wherein said at least one extension element is selected from the group comprising: a transversely-extending U-shaped element; a transversely-extending N-shaped element; a transversely-extending V-shaped element; and a longitudinally-extending S-shaped element.

22. The stent of claim 20, wherein said at least one extension element has an initial included angle of about 0°, the angular expansion of said initial included angle being limited to less than 180° upon extension of said at least one extension element.

23 The stent of claim 22, wherein said angular expansion is limited to less than 150°.

24. The stent of claim 23, wherein said angular expansion is limited to about 90° or less.

25. The stent of claim 20, wherein said at least one extension element has an initial acute included angle which is angularly expandable to an angle of less than 180° upon extension of said at least one extension element.

26. The stent of claim 25, wherein said initial acute included angle is angularly expandable to an angle of less than 150°.

27. The stent of claim 26, wherein said initial acute included angle is angularly expandable to an angle of about 90° or less.

28. The stent of claim 19, wherein said first and second members each include a flexuous extension element.

29 The stent of claim 2, wherein said medial member has a substantially circumferentially linear shape.

30. The stent of claim 2, wherein said medial member is lengthwise extensible.

31. The stent of claim 30, wherein said medial member includes at least one extension member.

32. The stent of claim 31, wherein said at least one extension member is selected from the group comprising: a transversely-extending U-shaped member; a transversely-extending N-shaped member; a transversely-extending V-shaped member; and a longitudinally-extending S-shaped member.

33. The stent of claim 31, wherein said at least one extension member has an initial included angle of about 0°, the angular expansion of said initial included angle being limited to less than 180° upon extension of said at least one extension member.

34. The stent of claim 33, wherein said angular expansion is limited to less than 150°.

35. The stent of claim 34, wherein said angular expansion is limited to about 90° or less.

36. The stent of claim 31, wherein said at least one extension member has an initial acute included angle which is angularly expandable to an angle of less than 180° upon extension of said at least one extension member.

37. The stent of claim 36, wherein said initial acute included angle is angularly expandable to an angle of less than 150°.

38. The stent of claim 37, wherein said initial acute included angle is angularly expandable to an angle of about 90° or less.

39. The stent of claim 30, wherein said medial member includes a flexuous extension member.

40. The stent of claim 2, wherein each serpentine element has a configuration which is substantially the same as each circumferentially adjacent serpentine element.

41. The stent of claim 2, wherein each ring comprises an even number of serpentine elements and wherein the configuration of each serpentine element is a substantially mirrored-image of a circumferentially adjacent serpentine element of said ring.

42. The stent of claim 2, wherein said first end of said first member is connected to said second end of said second member of a circumferentially adjacent serpentine element of said ring by a connection member.

43. The stent of claim 42, wherein said connection member is generally linear and is disposed substantially parallel to the longitudinal axis of the stent when in its constricted state.

44. The stent of claim 43, wherein the connection member connects to said first end of said first member and to said second end of said second member of said circumferentially adjacent serpentine element by plastically bendable joints.

45. The stent of claim 44, wherein said plastically bendable joints form a rounded corner between said first member and said medial member and between said second member and said medial member.

46. The stent of claim 44, wherein said plastically bendable joints form an angled corner between said first member and said medial member and between said second member and said medial member.

47. The stent of claim 44, wherein said plastically bendable joints form an initial included angle between said first member and said medial member and between said second member and said medial member of approximately 90°.

48. The stent of claim 47, wherein angular expansion of said initial included angle is limited to an angle of less than 180°.

49. The stent of claim 48, wherein angular expansion of said initial included angle is limited to an angle of less than 150°.

50. The stent of claim 42, wherein said connection member is expandable to increase the distance between the first end of said first member second end of said second member of a circumferentially adjacent serpentine element.

51. The stent of claim 50, wherein said connection member includes at least one expansion segment.

52. The stent of claim 51, wherein said expansion segment is selected from the group comprising: a transversely-extending U-shaped segment; a transversely-extending N-shaped segment; a transversely-extending V-shaped segment; and a longitudinally-extending S-shaped segment.

53. The stent of claim 51, wherein said at least one expansion segment has an initial included angle of about 0°, the angular expansion of said initial included angle being limited to less than 180° upon extension of said at least one expansion segment.

54. The stent of claim 53, wherein said angular expansion is limited to less than 150°.

55. The stent of claim 54, wherein said angular expansion is limited to about 90° or less.

56. The stent of claim 51, wherein said at least one expansion segment has an initial acute included angle which is angularly expandable to an angle of less than 180° upon extension of said at least one expansion segment.

57. The stent of claim 56, wherein said initial acute included angle is angularly expandable to an angle of less than 150°.

58. The stent of claim 57, wherein said initial acute included angle is angularly expandable to an angle of about 90° or less.

59. The stent of claim 50, wherein said connection member includes a flexuous expansion segment.

60. The stent of claim 50, wherein the connection member connects to said first end of said first member and to said second end of said second member of said circumferentially adjacent serpentine element by plastically bendable joints.

61. The stent of claim 60, wherein said plastically bendable joints form a rounded corner between said first member and said connecting member and between said connecting member and said second member of said circumferentially adjacent serpentine element.

62. The stent of claim 60, wherein said plastically bendable joints form an angled corner between said first member and said connecting member and between said connecting member and said second member of said circumferentially adjacent serpentine element.

63. The stent of claim 60, wherein said plastically bendable joints form an initial included angle of approximately 90° between said first member and said connecting member and between said connecting member and said second member of said circumferentially adjacent serpentine element.

64. The stent of claim 63, wherein angular expansion of said initial included angle is limited to an angle of less than 180°.

65. The stent of claim 64, wherein angular expansion of said initial included angle is limited to an angle of less than 150°.

66. The stent of claim 2, wherein adjacent pairs of radially expandable rings are interconnected by at least one interconnecting member disposed generally parallel with said longitudinal axis.

67. The stent of claim 66, wherein said interconnecting member connects one of said circumferentially-extending members of one serpentine element with a corresponding one of said circumferentially-extending members of another serpentine element of an adjacent ring.

68. The stent of claim 20, wherein adjacent pairs of radially expandable rings are interconnected by at least one interconnecting member disposed generally parallel with said longitudinal axis.

69. The stent of claim 68, wherein said interconnecting member connects one extension element of one of said circumferentially-extending members of one serpentine element to a corresponding extension element of a corresponding one of said circumferentially-extending members of another serpentine element of an adjacent ring.

70. The stent of claim 18, wherein adjacent pairs of said radially expandable rings are interconnected by integrally forming one of said circumferentially-extending members of one serpentine element along side with a corresponding one of said circumferentially-extending members of another serpentine element of an adjacent ring.

71. The stent of claim 20, wherein adjacent pairs of said radially expandable rings are interconnected by attaching at least one extension element of one of said circumferentially-extending members of one serpentine element to a corresponding extension element of a corresponding one of said circumferentially-extending members of another serpentine element of an adjacent ring.

72. The stent of claim 42, wherein adjacent pairs of radially expandable rings are interconnected by at least one interconnecting member and wherein each said interconnecting member connects one of said connecting members of one ring with an adjacent one of said connecting members of an adjacent ring.

73. The stent of claim 51, wherein adjacent pairs of radially expandable rings are interconnected by at least one interconnecting member and wherein each said interconnecting member connects an expansion segment of a connecting member with an adjacent expansion segment of a connecting member of an adjacent ring.

74. The stent of claim 66, wherein said interconnecting member includes at least one longitudinally extendable section.

75. The stent of claim 74, wherein said at least one extendable section is selected from a group comprising: a transversely-extending U-shaped section; a transversely-extending N-shaped section; a transversely-extending V-shaped section; and a longitudinally-extending S-shaped section.

76 The stent of claim 71, wherein said at least one extendable section has an initial included angle of about 0°, the angular expansion of said initial included angle being limited to less than 180° upon extension of said at least one extendable section.

77. The stent of claim 76, wherein said angular expansion is limited to less than 150°.

78. The stent of claim 77, wherein said angular expansion is limited to about 90° or less.

79. The stent of claim 71, wherein said at least one extendable section has an initial acute included angle which is angularly expandable to an angle of less than 180° upon extension of said at least one expansion segment.

80. The stent of claim 79, wherein said initial acute included angle is angularly expandable to an angle of less than 150°.

81. The stent of claim 80, wherein said initial acute included angle is angularly expandable to an angle of about 90° or less.

82. The stent of claim 71, wherein said interconnection member includes a flexuous extendable section.

83. The stent of claim 2, wherein the stent is made from a biocompatible material.

84. The stent of claim 83 wherein the biocompatible material is selected from a group comprising alloys of: silver; tantalum; stainless steel; gold; titanium; and nickel-titanium.

85. The stent of claim 2, wherein the stent is made from a radioactive material or a material irradiated with a radioactive isotope.

86. The stent of claim 85 wherein the radioactive isotope is a beta particle emitting isotope.

87. The stent of claim 2, wherein the stent is coated with a bioabsorbable medicinal or pharmaceutical substance.

88. The stent of claim 2, wherein the stent is coated with an anticoagulating substance.

89. The stent of claim 2, wherein the stent is made from a porous material containing a time-release drug.

90. The stent of claim 2, wherein said stent is fabricated from a work-hardenable material to limit expansion of said rings in proportion to the amount of expansion.

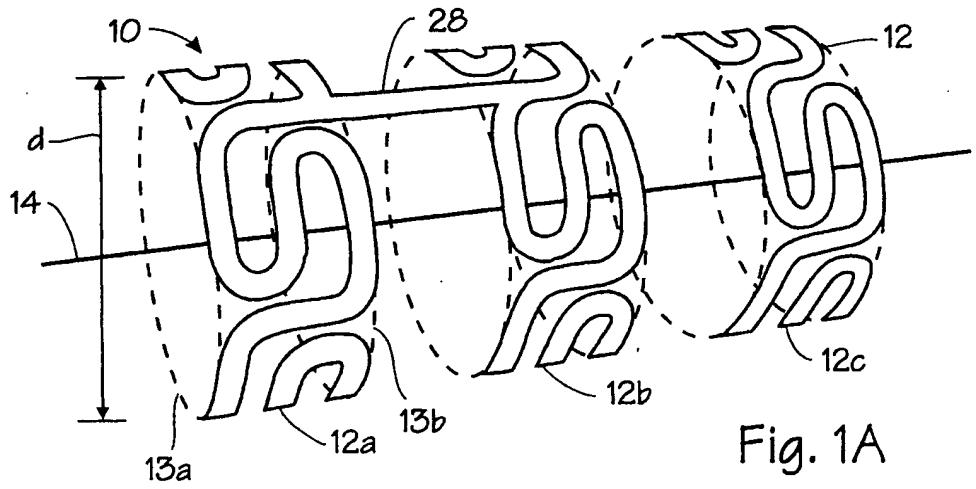

Fig. 1A

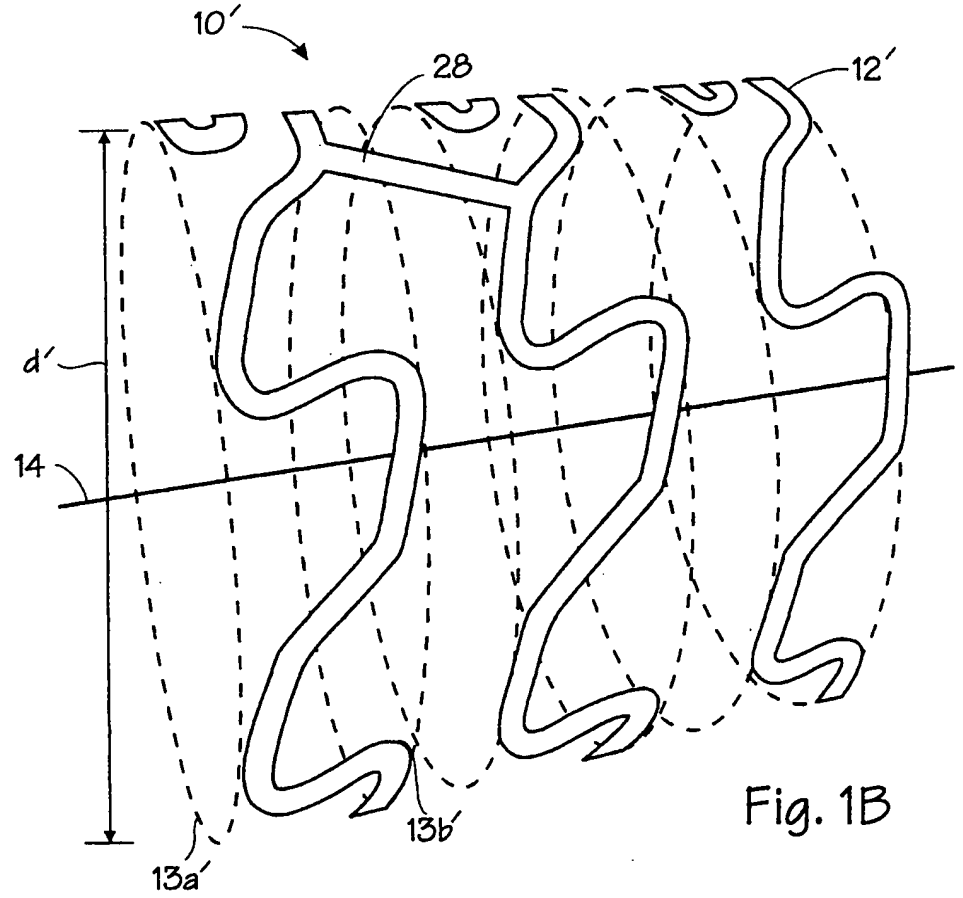

Fig. 1B

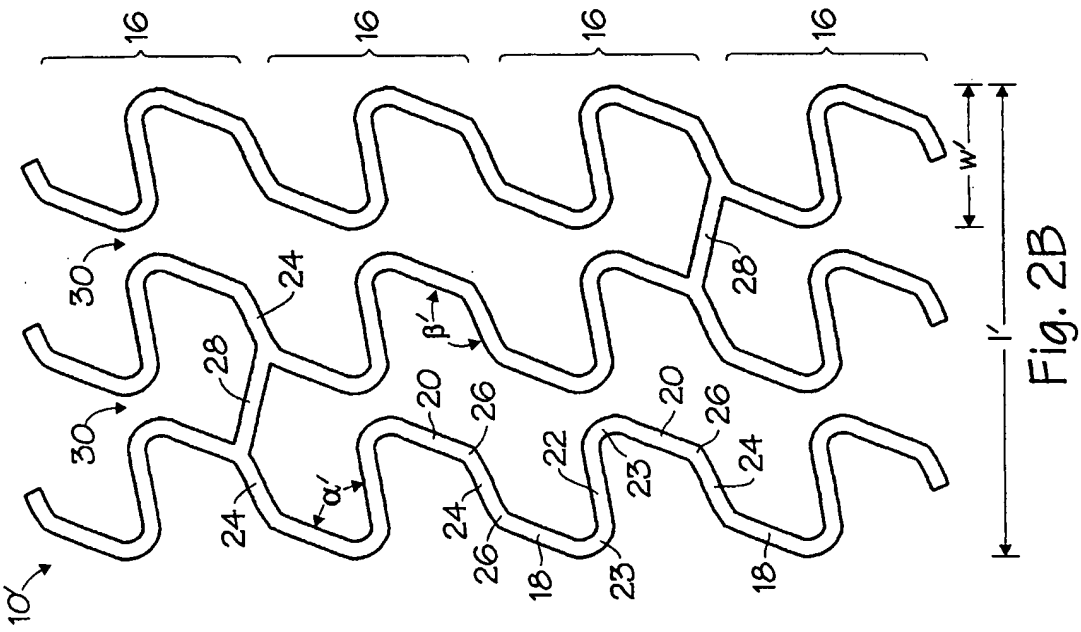
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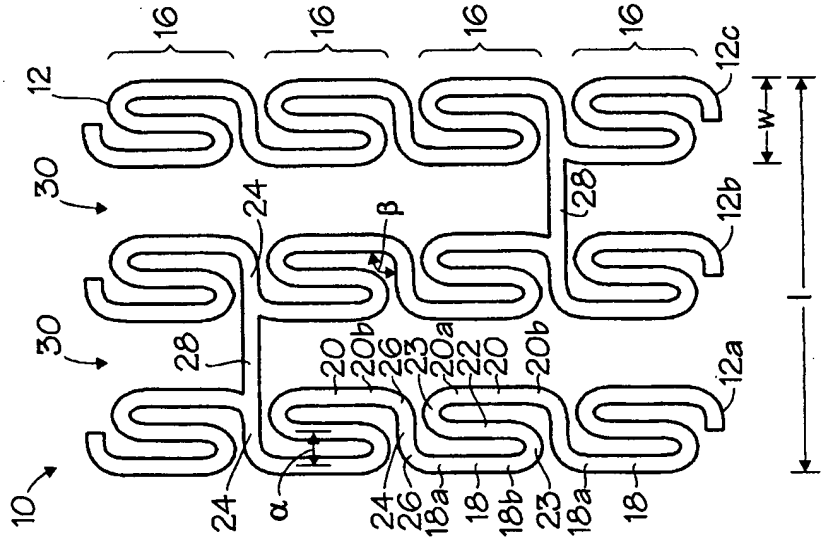
Fig. 2B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12b
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Fig. 2A

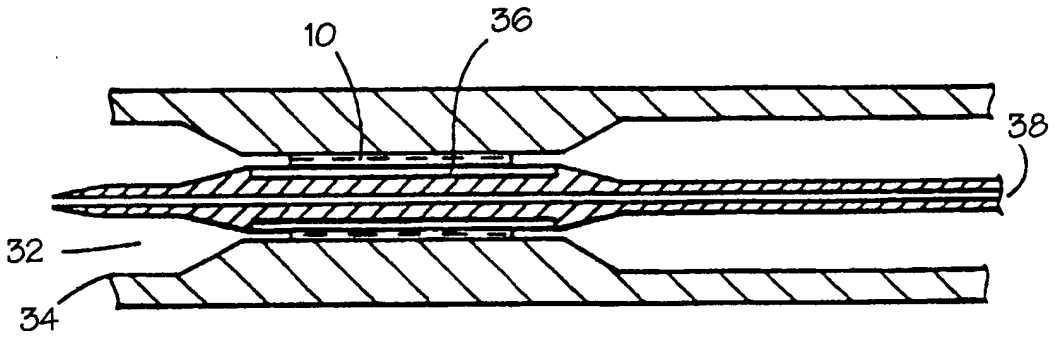

Fig. 3A

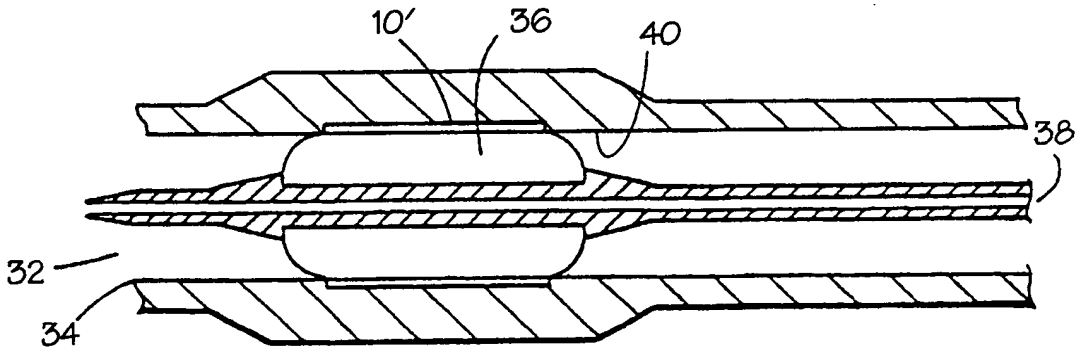

Fig. 3B

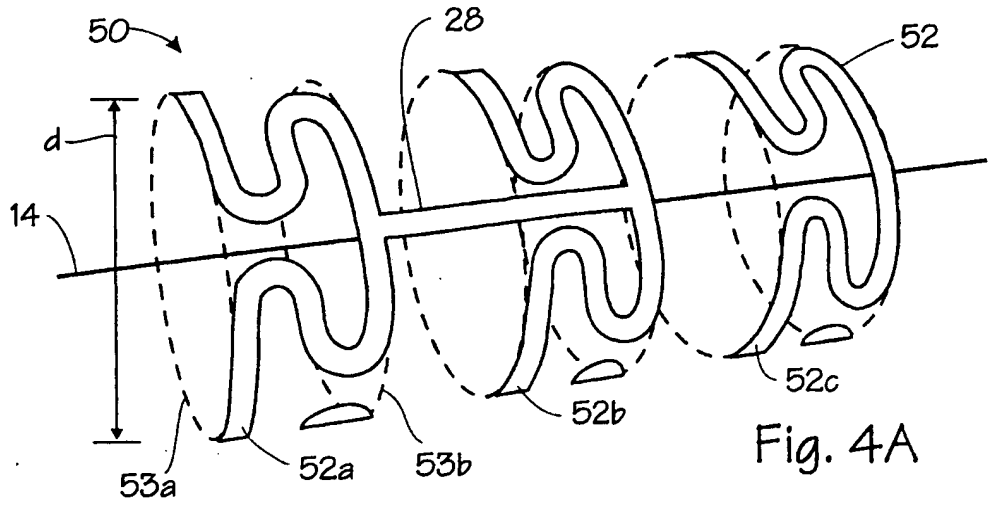

Fig. 4A

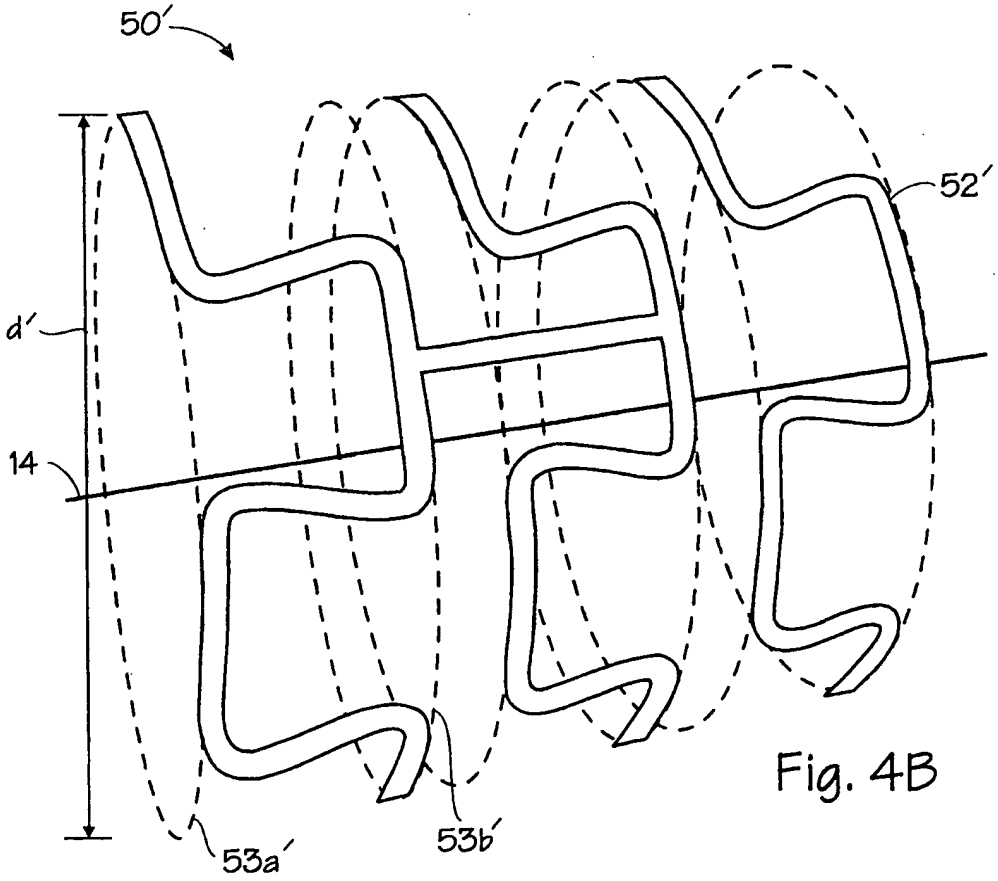

Fig. 4B

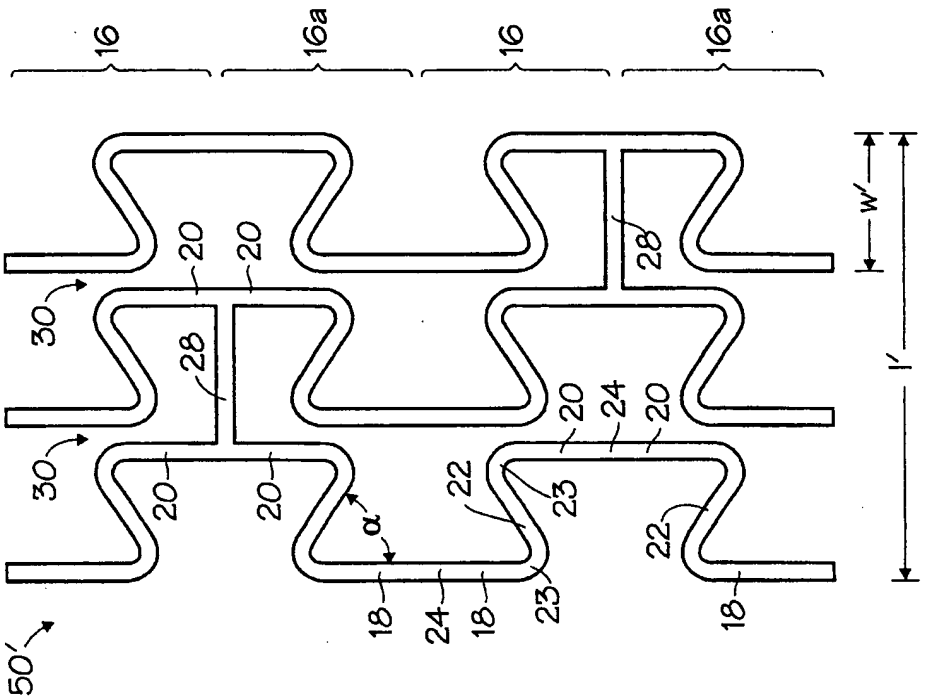
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Fig. 5B

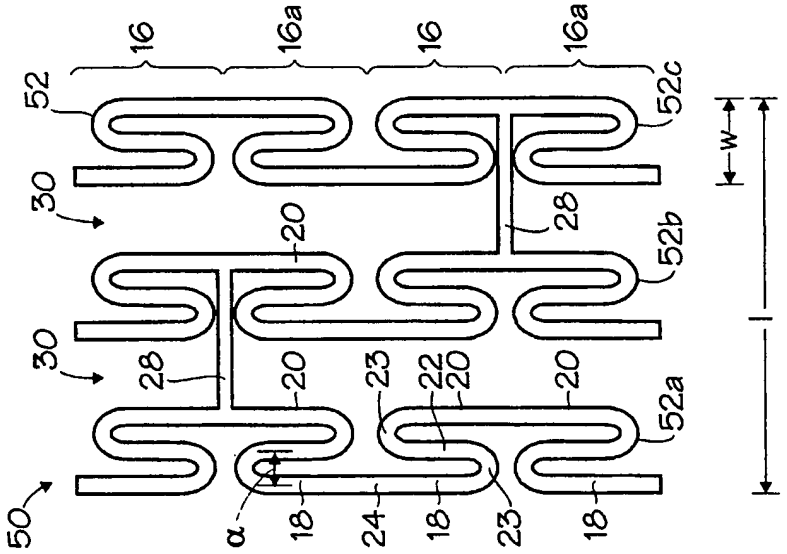
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Fig. 5A

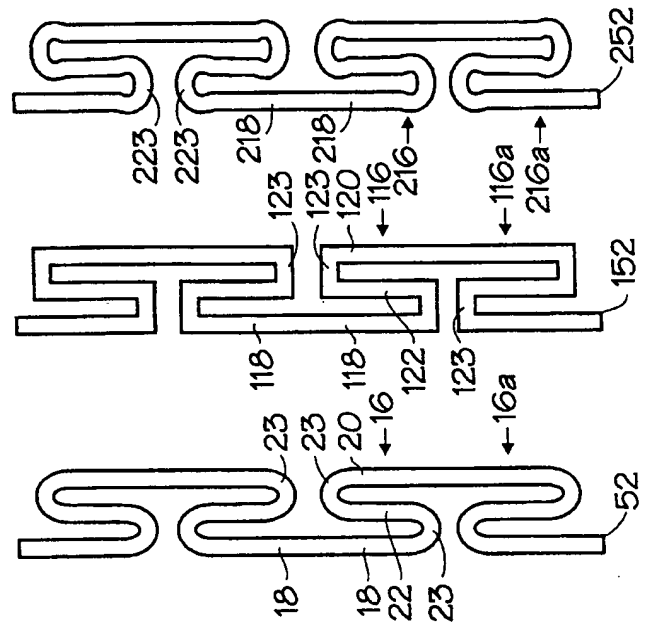


Fig. 7A Fig. 7B Fig. 7C

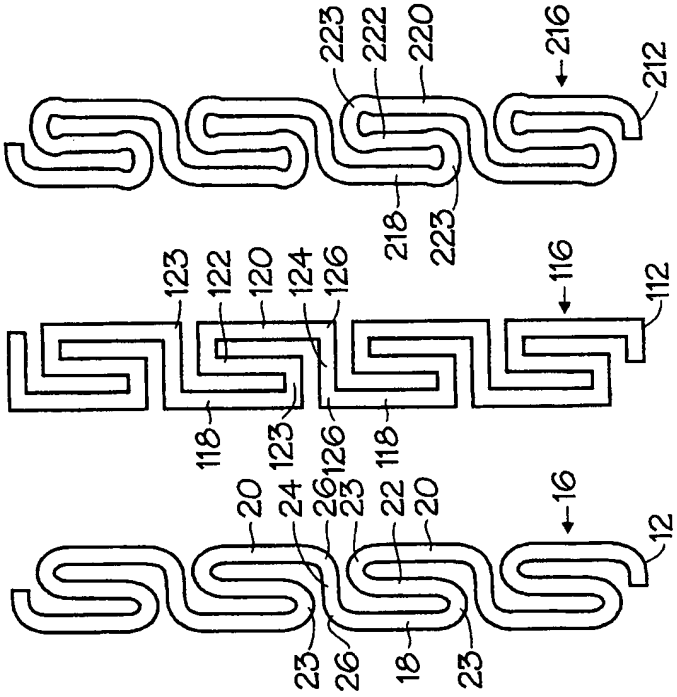


Fig. 6A Fig. 6B Fig. 6C

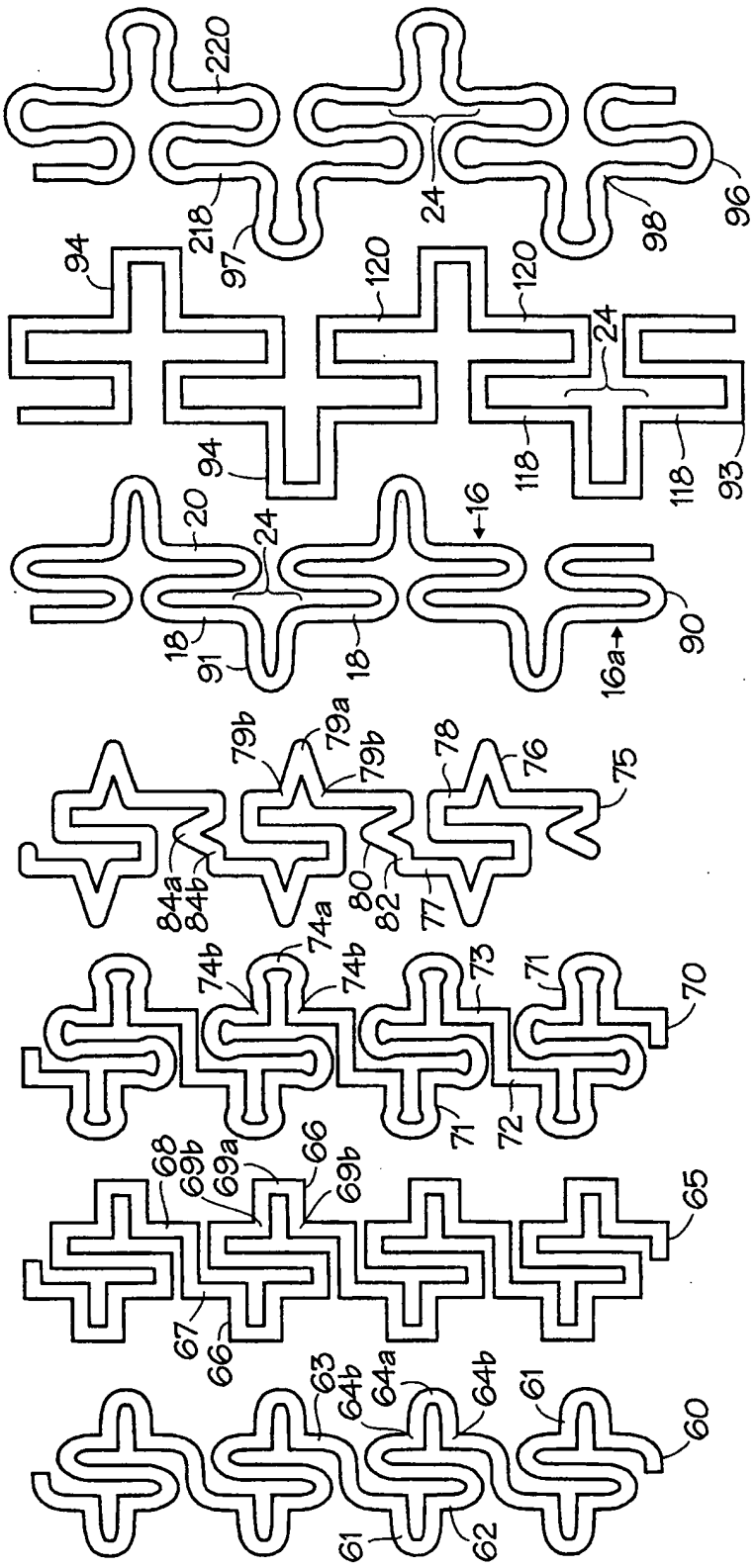
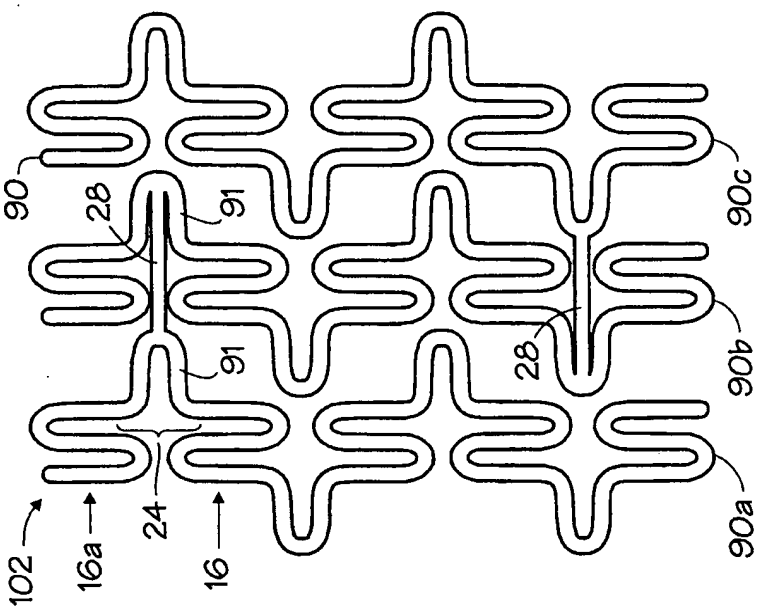


Fig. 8A Fig. 8B Fig. 8C Fig. 8D Fig. 9A Fig. 9B Fig. 9C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16a
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Fig. 11

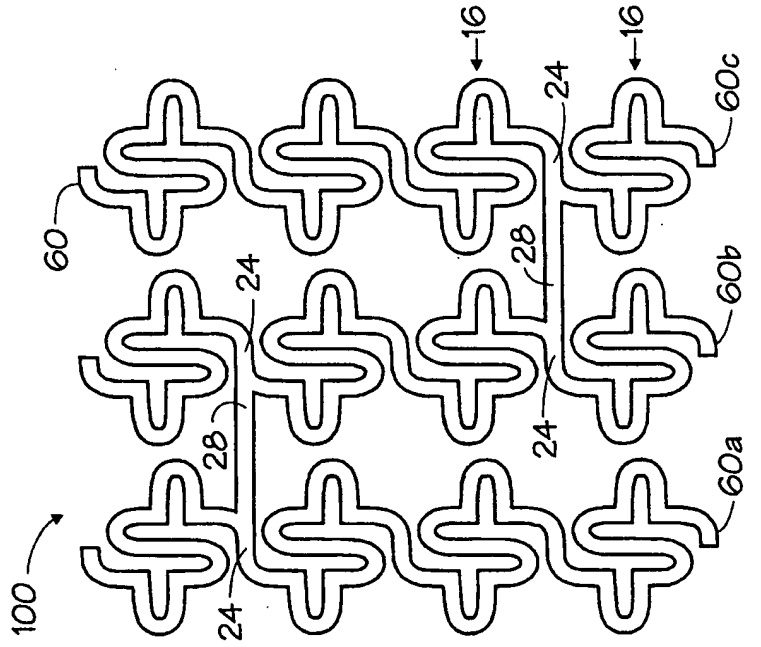
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Fig. 10

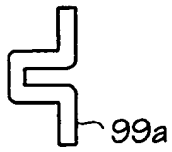

Fig. 12A

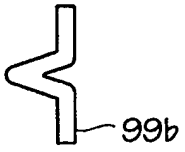

Fig. 12B

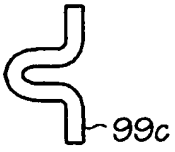

Fig. 12C

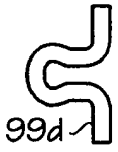

Fig. 12D

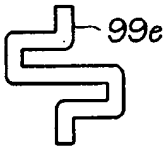

Fig. 12E

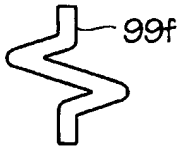

Fig. 12F

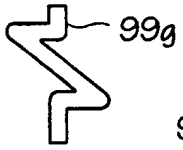

Fig. 12G

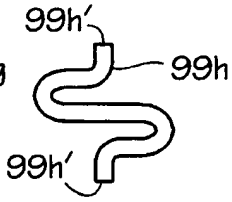

Fig. 12H

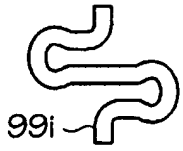

Fig. 12I

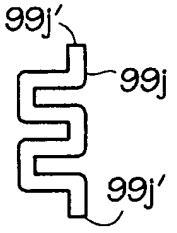

Fig. 12J

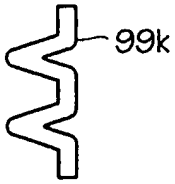

Fig. 12K

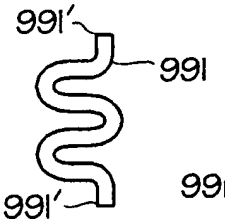

Fig. 12L

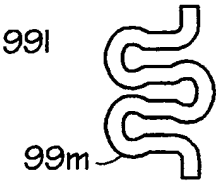

Fig. 12M

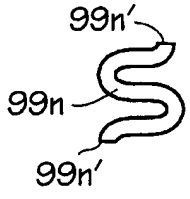

Fig. 12N

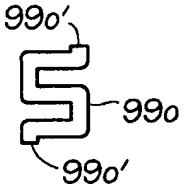

Fig. 12O

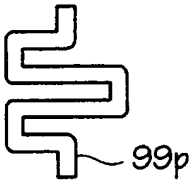

Fig. 12P

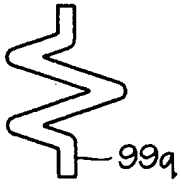

Fig. 12Q

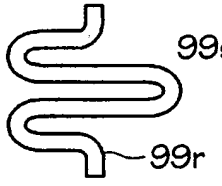

Fig. 12R

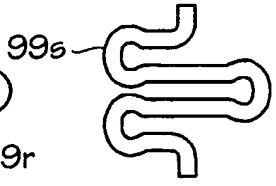

Fig. 12S

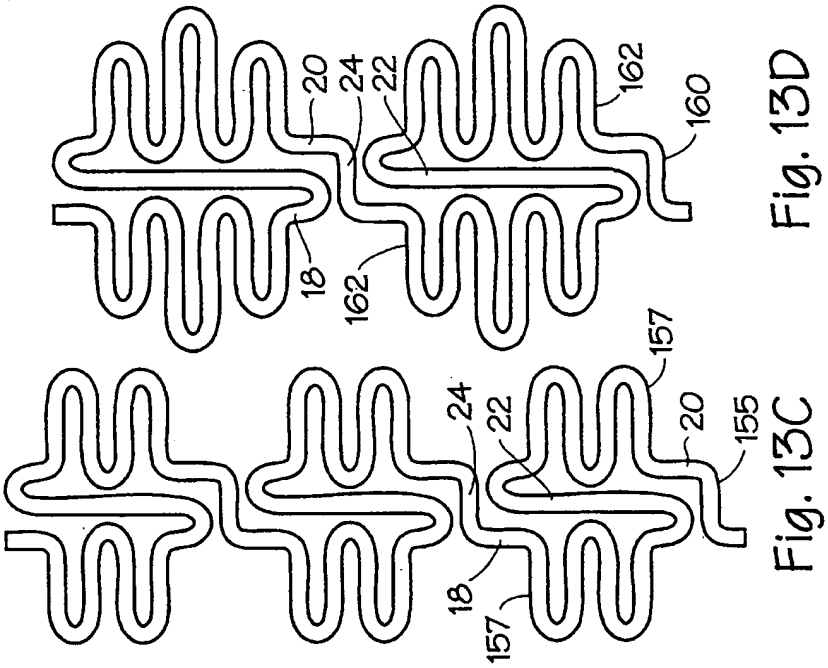

Fig. 13D

Fig. 13C

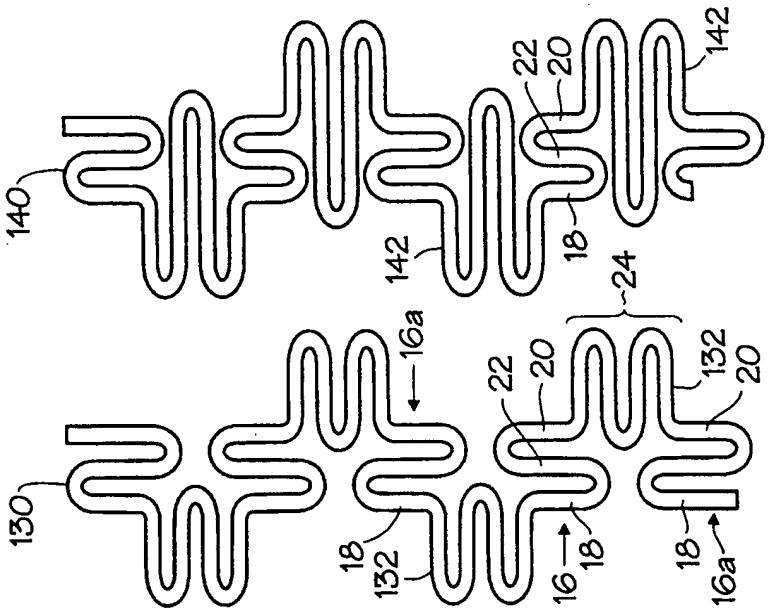

Fig. 13B

Fig. 13A

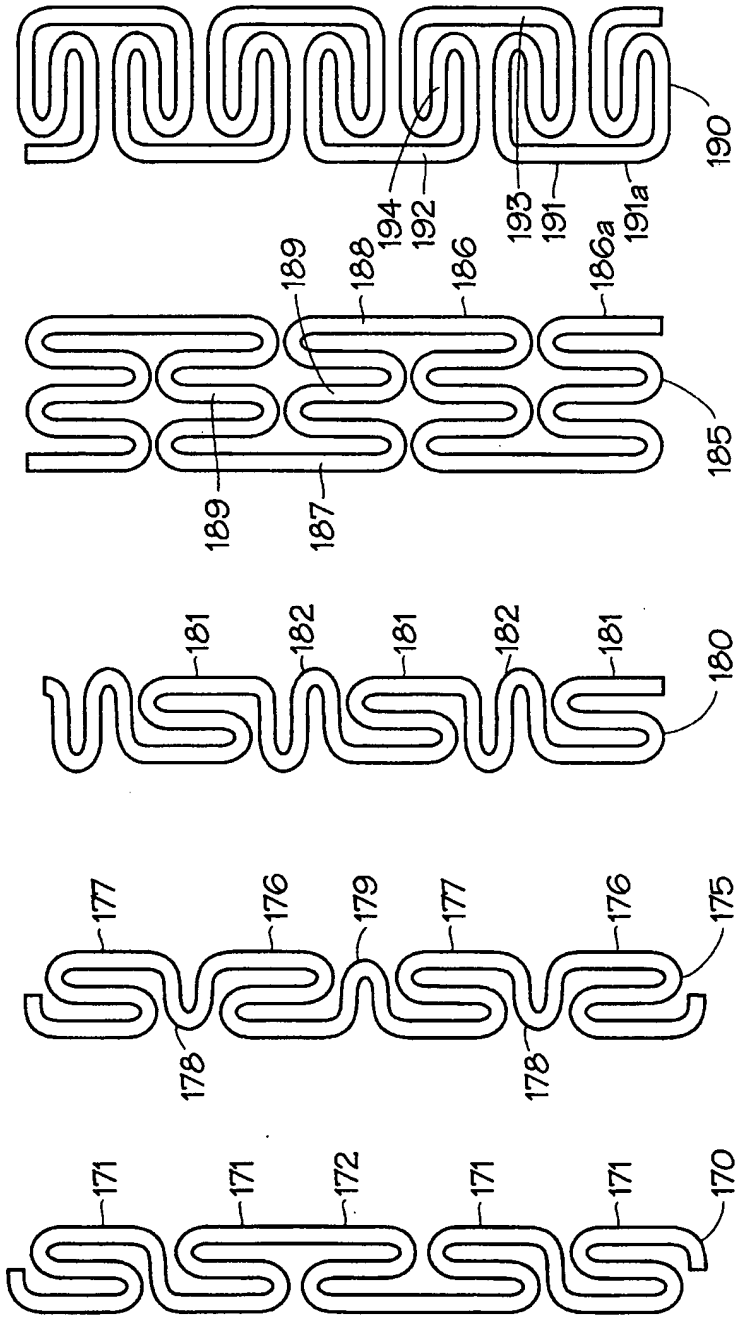

Fig. 14 Fig. 15A Fig. 15B Fig. 16 Fig. 17

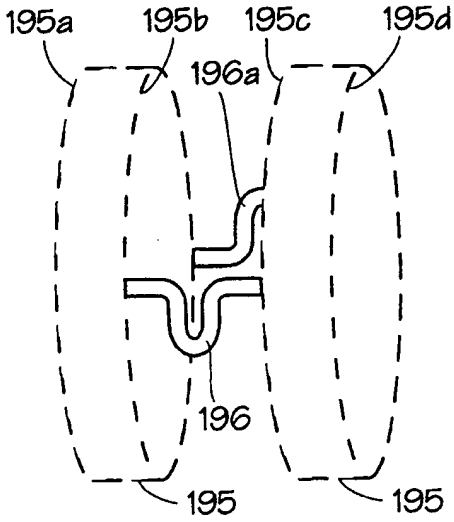

Fig. 18A

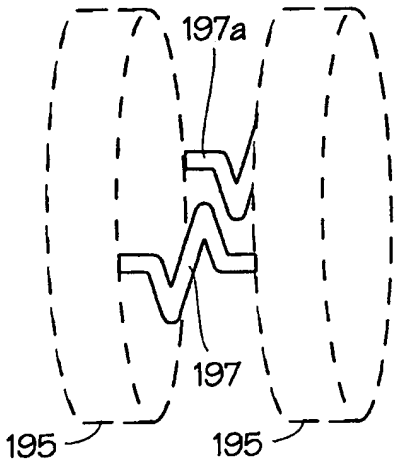

Fig. 18B

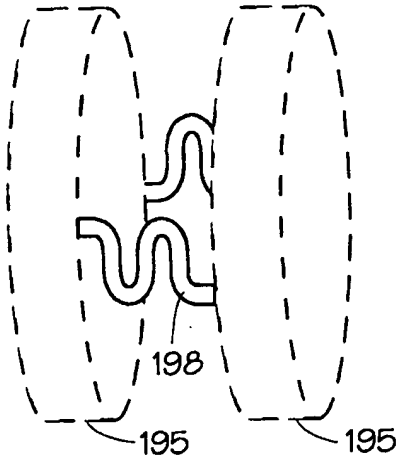

Fig. 18C

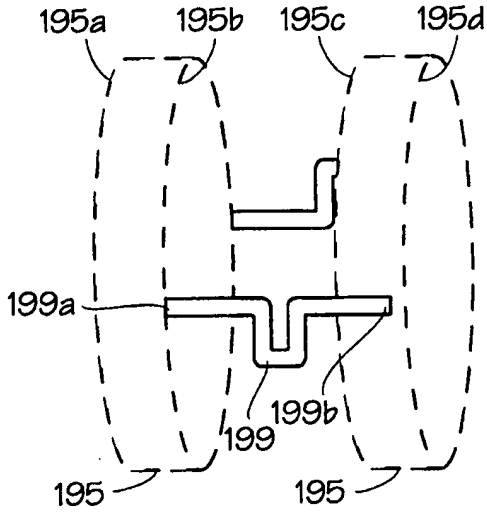

Fig. 18D

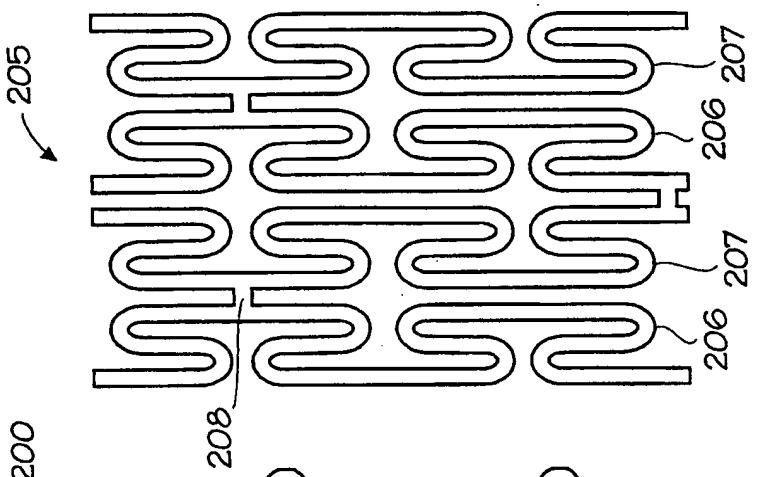
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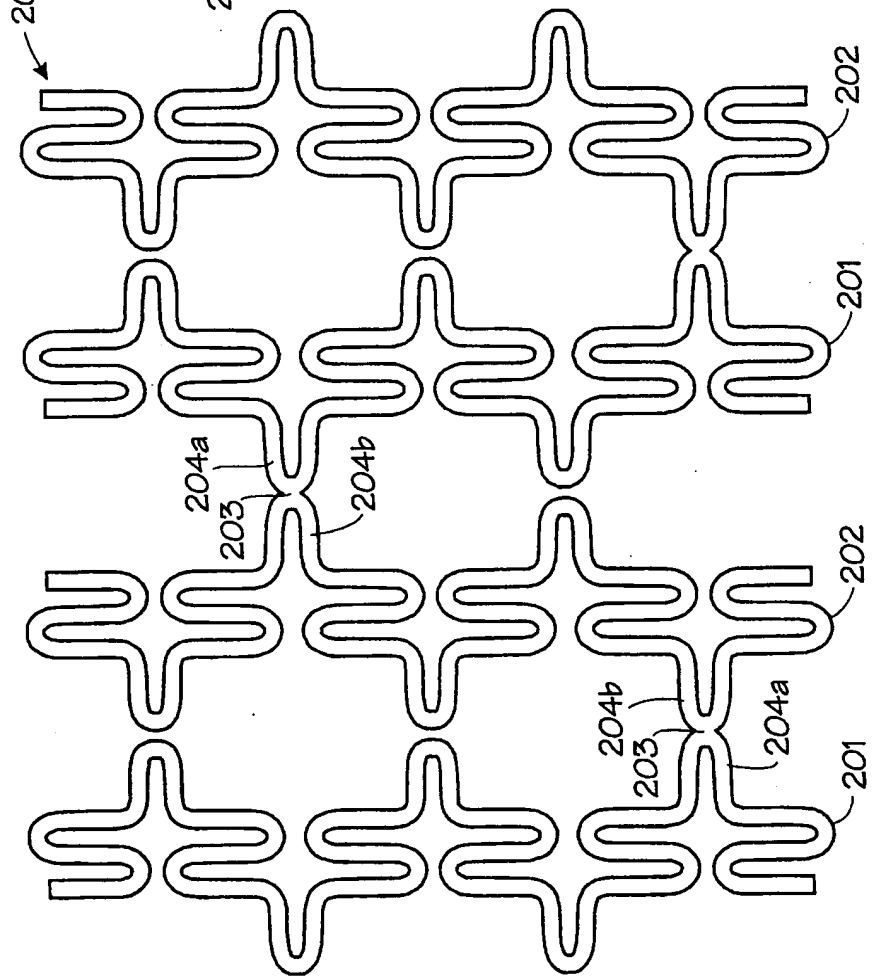
Fig. 20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204a
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Fig. 19

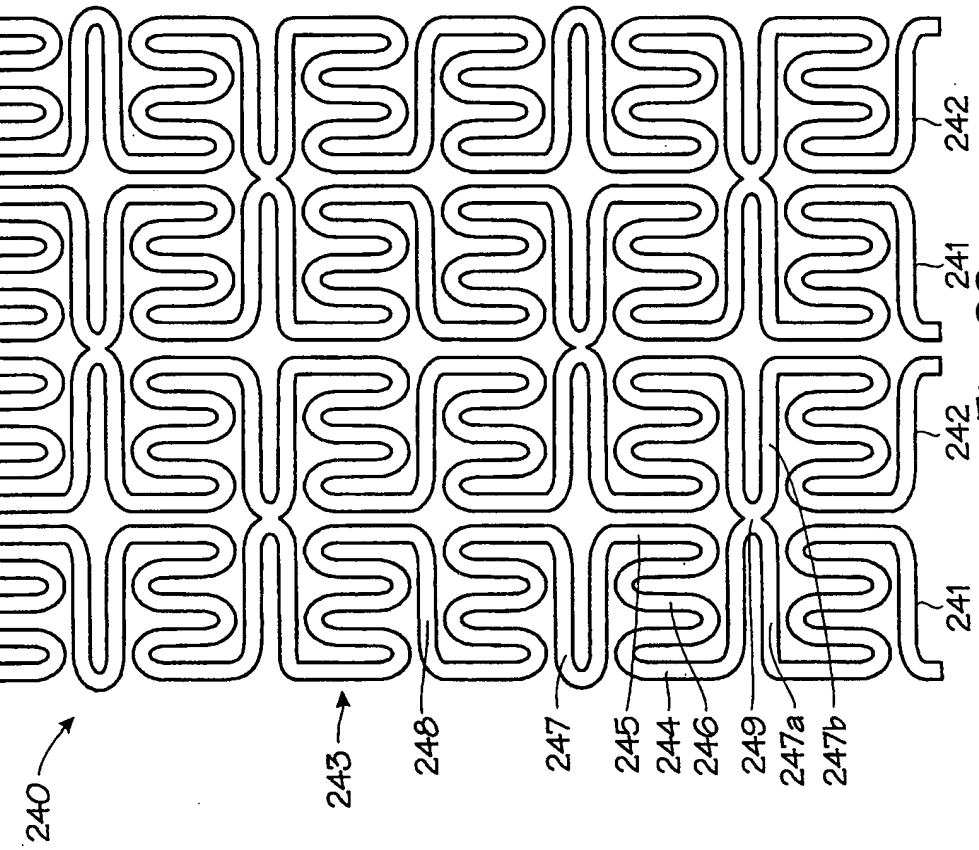
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Fig. 22

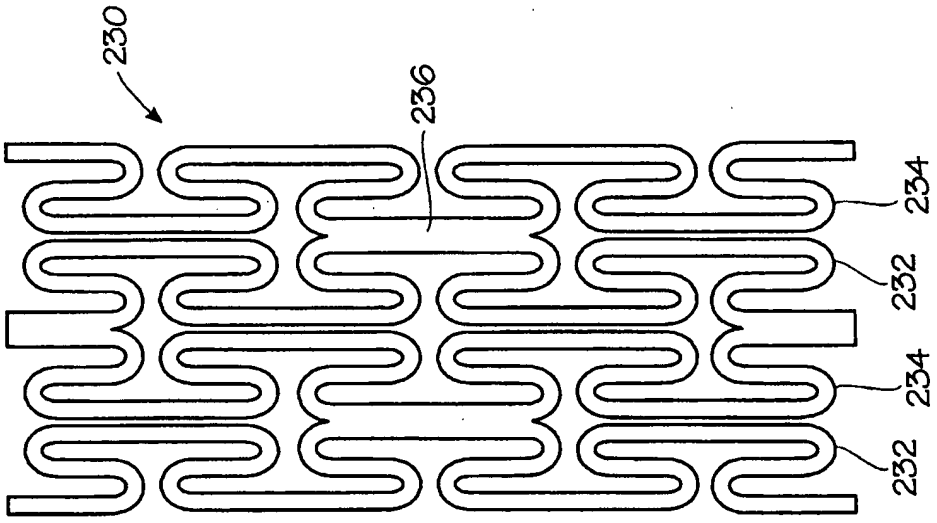
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Fig. 21

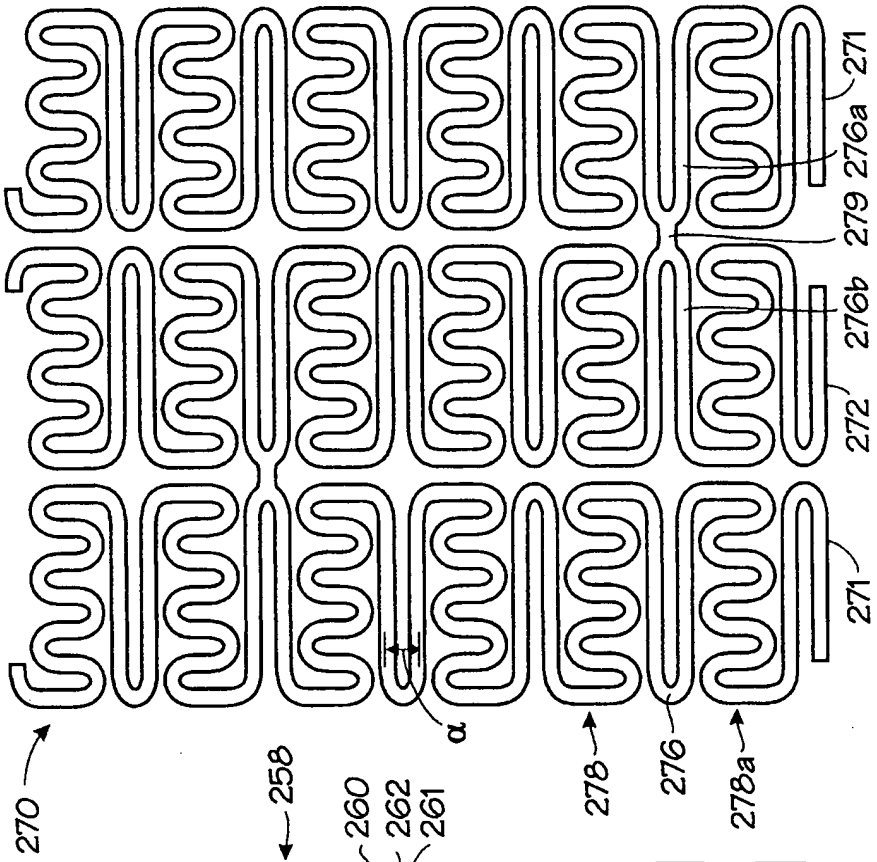
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Fig. 24

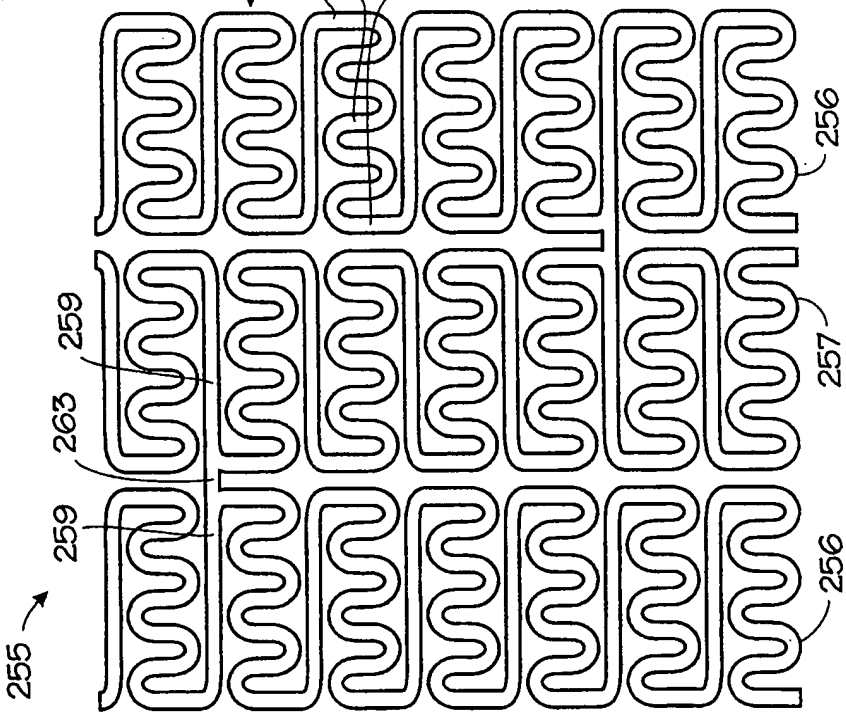
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Fig. 23

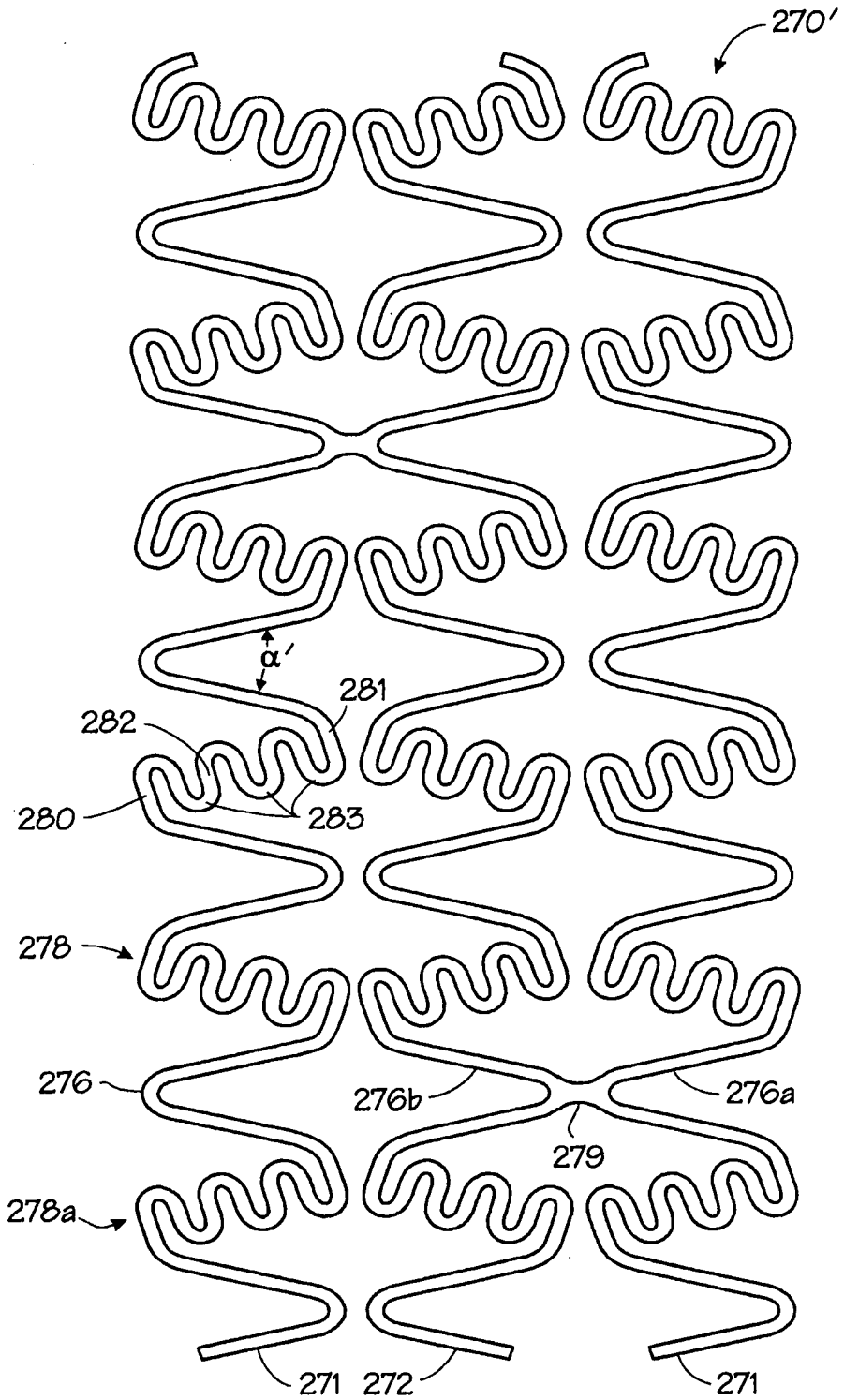

Fig. 25

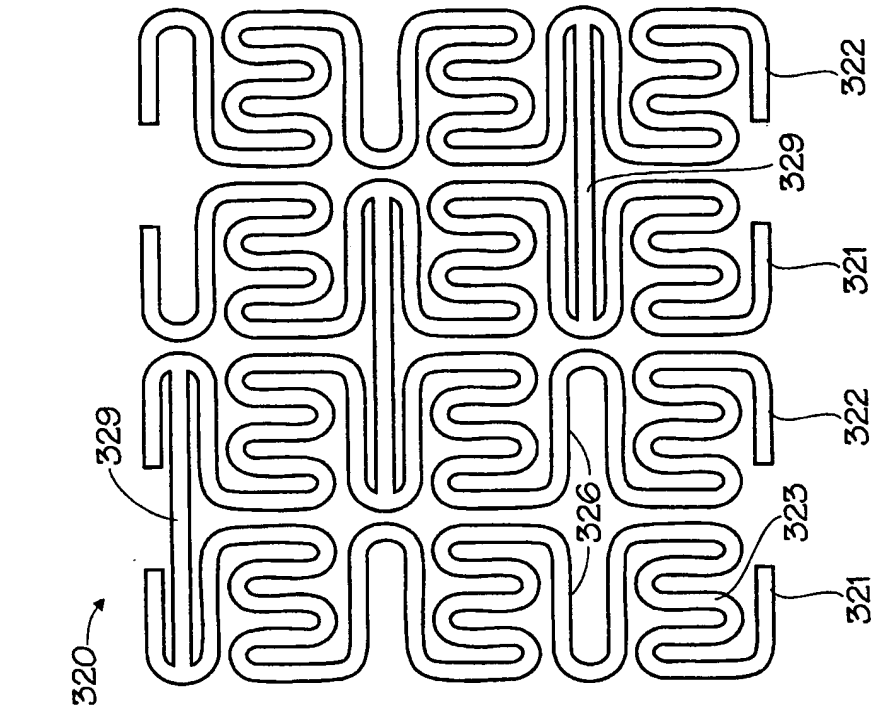
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Fig. 27

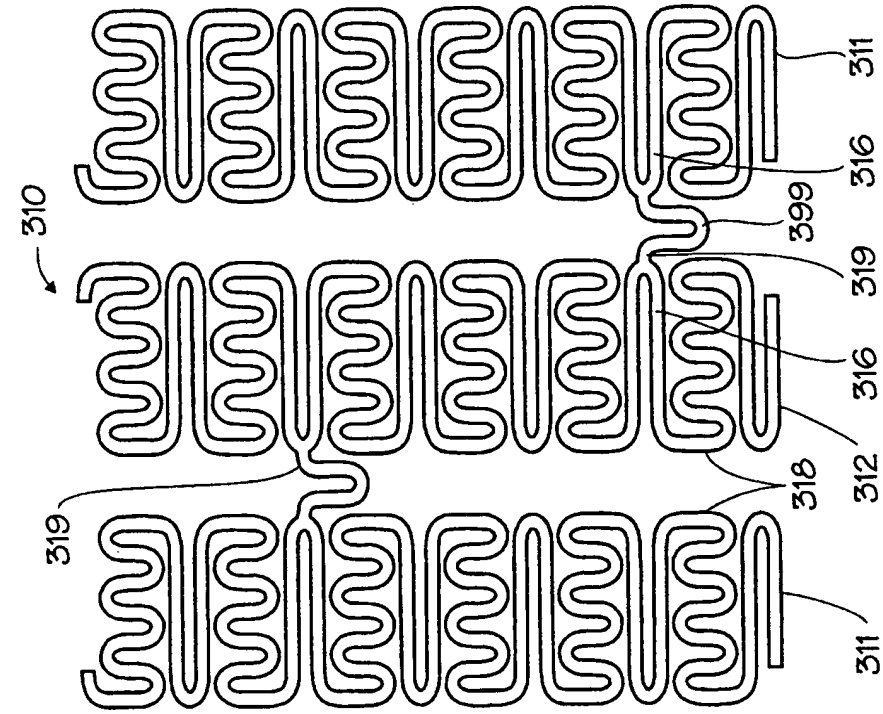
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Fig. 26

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/CA 99/00632

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 806 190 A (SORIN BIOMEDICA CARDIO SPA) 12 November 1997 (1997-11-12) column 11, line 32 -column 12, line 56 claims; figures 9-11 ---	1
E	WO 99 36002 A (ADVANCED STENT TECHN) 22 July 1999 (1999-07-22) page 13, line 3 -page 14, line 25 claims; figures 4,10-12 ---	1
E	EP 0 928 606 A (NITINOL DEV CORP) 14 July 1999 (1999-07-14) column 5, line 42 -column 10, line 39 claims 1-5; figures 3-7 ---	1
A	WO 99 17680 A (LOCALMED INC) 15 April 1999 (1999-04-15) claims; figures --- -/--	1-90

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 November 1999	13/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kuehne, H-C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/CA 99/00632

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